Mentoring Theme Issue

The Mentor-Mentee Cycle of Learning and Guiding in Medical Writing and Science

Snapshots of the 2012 Annual Conference

LinkedIn Recommendations: How to Make Them Work for You
The AMWA Journal expresses the interests, concerns, and expertise of members. Its purpose is to inspire, motivate, inform, and educate them. The Journal furthers dialog among all members and communicates the purposes, goals, advantages, and benefits of the American Medical Writers Association (AMWA) as a professional organization. Specifically, it functions to

➲ Publish articles on issues, practices, research theories, solutions to problems, ethics, and opportunities related to effective medical communication

➲ Enhance theoretical knowledge as well as applied skills of medical communicators in the health sciences, government, and industry

➲ Address the membership’s professional development needs by publishing the research results of educators and trainers of communications skills and by disseminating information about relevant technologies and their applications

➲ Inform members of important medical topics, ethical issues, emerging professional trends, and career opportunities

➲ Report news about AMWA activities and the professional accomplishments of its departments, sections, chapters, and members

The AMWA Journal is in the MLA International Bibliography and selectively indexed in the Cumulative Index to Nursing and Allied Health Literature (CINAHL) print index, the CINAHL database, and the Cumulative Index of Journals in Education (CIJE).

The opinions expressed by authors contributing to the Journal do not necessarily reflect the opinions of AMWA or the institutions with which the authors are affiliated. The association accepts no responsibility for the opinions expressed by contributors to the Journal.

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This issue of the AMWA Journal is my last as editor. Making the decision to step down was not easy. For the past 10 years, the Journal has been my passion. The work has been sometimes frustrating, often time-consuming, and always fulfilling. But, as I’ve said to anyone who’s asked, “Ten years is enough time for doing almost anything.” It is time for me to move on and, more important perhaps, it is time for another editor to put his or her mark on the Journal and bring it into a new era. I know that our new editor, Vicki White, will do just that, and I’m looking forward to her improvements to the Journal.

Vicki’s transition into the editorship should be easier than my own. When I took the helm in 2003, there had been no permanent editor in place for some time, so there was no one to explain established processes to me. I am forever grateful to Lynn Alperin, who had served as interim editor during the search, for her patience and guidance in helping me step into this important role. I am also thankful for Tom Gegeny, Marianne Mallia, and Helen Hodgson, three members of the Editor Search Committee, who offered unflagging support and availability during those first issues. These early relationships were not formal mentorships, but I did feel mentored.

Understanding the importance of mentorship, I have been committed to a mentoring relationship with Vicki, and we have worked as a team on these last issues and together developed this themed issue on mentorship. The feature article (page 147) presents a mentoring experience in an academic health care center’s grants office. You can read about three distinct mentoring experiences in the pharmaceutical world (beginning on page 169) and about educational experiences beyond mentorship in the continuing medical education world (page 166). And, you can find some blogs on mentoring (page 177), as well as a list of online resources (page 173).

And now, the reins are passed, and the experience is bittersweet. Aside from ending the honor of providing members with AMWA’s official publication, withdrawal was a serious concern. The thought of having 10 to 20 extra hours a month frightened me…whatever would I do with that time? Thankfully, our president, Doug Haneline, came to my rescue and asked me to serve as the 2013 Annual Conference Administrator. I happily accepted, pleased to fill those hours (what’s sleep, anyway?). The position will allow me to continue something I love—collaboration.

Collaboration indeed is what has helped me enhance the Journal over the years. When I became editor, I knew few people in AMWA, and the responsibility of the Journal forced me to talk to “strangers.” I needed to ask AMWA members what they want to see in the Journal, invite members to work on the Journal, and solicit members—and nonmembers—for manuscripts. The Journal opened a door, and I found a world of AMWA colleagues who were eager to help with the Journal. With them, the Journal moved from a simple publication to a more complex one in terms of both content and design (Figure 1). The evolution of the Journal’s design is due to the talent of Amy Boches, of biographics, who has been a loyal partner in the design and production of the Journal.

The Journal has provided me with countless rewards. It has given me the opportunity to talk with AMWA leaders about their vision for AMWA and initiatives to enhance our association. AMWA leaders have been an inspiration to me over the years, and I look forward to their continued support and mentoring.

The Journal has presented the chance to work closely with staff at AMWA headquarters, who today is an amazing collection of bright and enthusiastic partners with AMWA leaders. I thank them for their support in producing the Journal and in exploring new ways to deliver content to members.

Perhaps most important, the Journal has offered the opportunity to work extensively with an outstanding volunteer staff. I am thankful for the section editors, regular contributors, peer reviewers, manuscript editors, and proofreaders who have been dedicated to the Journal, some for several years. These volunteers not only made my job easier but they also made me look good—issue after issue. I am forever grateful for their time, commitment, and ongoing friendship.

All good things must come to an end. And so my editorship ends.
ABSTRACT
The Office of Grants and Scientific Publications (OGSP) was established at the University of Arkansas for Medical Sciences (UAMS) nearly 20 years ago. UAMS is a tertiary referral center and Arkansas’ only comprehensive academic health care center. The staff at OGSP have helped hundreds of UAMS faculty, fellows, and residents obtain research funding and publications. Our services encompass one-on-one interactions between editors and investigators over the course of an editing project, in addition to workshops and seminars that extend the mentoring experience, with the goal of increasing the quality of the grants and manuscripts we receive. This article outlines the strategies we have adopted to most efficiently meet the various needs of our investigators while exploring new methods for tracking success rates. We believe the mentoring experience provided by our office results in a more effective editing job and, ultimately, successful outcomes with regard to grant funding and manuscript publication.

INTRODUCTION
The Office of Grants and Scientific Publications (OGSP) had its origins when a clinician scientist at the University of Arkansas for Medical Sciences (UAMS) recognized the value of having a professional medical writer edit a previously unfunded grant application. As a result of the endeavor, the writer was hired full-time and eventually became the first director of OGSP. Soon after, two additional editors and a budget specialist were hired because of high workload. The OGSP was ultimately officially established in 1995 as a UAMS shared resource, with administrative oversight provided by the Vice Chancellor for Research. Since then, our office, currently with a staff of seven, has helped hundreds of our university scientists obtain research funding and see their work get published.

UAMS is a tertiary referral center and Arkansas’ only comprehensive academic health center, with five colleges and a graduate school (see Figure 1). Although OGSP is not unique among academic health care institutions and teaching hospitals, shared resources similar to our office remain uncommon. An assessment of US medical school websites conducted in 2007 by our office indicated 11 similar research resources out of the 124 schools examined, excluding individual departments that may have hired a single science editor to help with grants and manuscripts.

HOW OGSP WORKS
The Investigator/Editor Relationship
One of our goals as editors is to develop a good investigator/editor relationship that will facilitate mentoring on our part and trust on the investigator’s part. This often begins with a face-to-face meeting. The investigator and, possibly, other members of his or her research team meet with the manager of our
office and with the editor most suited, by expertise and availability, to work on the proposed project. The overall deadline is confirmed (including internal procedural requirements), and interim deadlines are established.

This initial meeting also gives the editor the opportunity to discuss the investigator’s research. It is during this informal discussion that key phrases and optimum wording can be identified for a specific application and intended audience. In fact, the enthusiasm displayed by a researcher during this initial discussion of his or her work can substantially help the editor emphasize its impact and significance—key terms used to judge a grant’s fundability at, for example, the National Institutes of Health (NIH). Because grant applications and journal articles are formal scientific documents, many researchers mistakenly rely on very complicated language constructions or a slew of acronyms to communicate their research. As a result, all excitement for the project is lost in a quagmire of technical language. However, a simple discussion with the investigator can tease out the crux of what he or she hopes to accomplish, providing a way for the editor to invigorate the piece with the same excitement that sparked the research in the first place.

An iterative editing process then follows, with questions and concerns posed by the editor, which are addressed by the investigator in subsequent drafts. This seems to work best for most investigators as well as for our editing team. We use Microsoft Word as our word processing system and apply the track changes feature and comments tool, so the investigator can see both where and why text has been moved, deleted, or altered. We typically see three or more drafts of a grant proposal, and two to three drafts of a manuscript before submission. Some investigators prefer to discuss these iterations during face-to-face meetings while others opt to use e-mail or other communications, such as telephone calls, instead. We do our best to accommodate these preferences.

We try to schedule editing projects to allow for substantive revisions and multiple iterations, preferably starting on an editing job at least a month before the deadline; however, this is not always possible. We still try to accommodate requests that come in just before a deadline by providing a more limited editorial service. For example, if we have only 4 hours to work on a grant, we will offer to review the Specific Aims and provide feedback.

Although junior investigators who are new to the funding arena would seem to be the focus of our mentoring endeavors, we have found that more seasoned investigators request our services because of the increasingly competitive funding environment. The concepts of grantsmanship that we try to impart are as equally useful to these individuals, particularly in light of the revised format of NIH grants (described on the next page), which necessitates a writing style that is more akin to marketing and advertising than to scientific writing.

Program Project Grants
The Program Project grant application, which involves several investigator-led projects, probably represents the greatest challenge for our editing team because of its multiple components and, often, multidepartmental nature. Not only is the grant application more complex, the need for stylistic and content consistency among component parts means a whole new level of editing must take place. We accomplish this by pairing editors with individual project leaders—again establishing good investigator/editor relationships that foster a mentoring approach.

Once individual projects or component parts have been edited and finalized, the editing team checks for consistency. Although our office follows standard style manuals, such as those published by the American Medical Association and the Council of Science Editors, we also established a style guide “cheat sheet” for use with multi-component projects early on during the editing process. This sheet briefly lists the proper use of definitions and acronyms, as well as the proper format for words and phrases, for example, when to italicize or hyphenate. We also include stylistic preferences suggested by the principal investigator, so that everyone is in agreement when it comes time to proofread a final copy.

Budgets and Forms
Easily half of a final grant application is composed of pages that do not discuss the actual research. This includes the reams of standard forms (e.g., biosketches, budgets, facilities, and resource descriptions) that make up what we call the “front and back matter.” Unfortunately, many researchers pay less attention to these sections, as the primary focus is the research plan. For this reason, OGSP has had a budget specialist on staff, although this position is currently vacant. We have found that the services of this individual are in high demand; many researchers do not wish to employ the work of an editor but can certainly use help with the budgets and forms.

We take advantage of two existing systems to help complete these standard forms. First, we use available material and information as much as possible, such as institutional resources that remain similar from year to year. Second, our institution’s website has in-depth information that can be tailored to the requirements of a specific proposal. We have also developed several Excel spreadsheets that enable the budget specialist to more easily and accurately populate the required budget sheets.

EXTENDING THE MENTORING EXPERIENCE
To our knowledge, grant writing, and in many cases manuscript writing, is not typically a part of the standard course curriculum in either graduate school or medical school. Unless an experienced faculty member has the time and
opportunity to provide this instruction, many students enter residency or post-doctoral training having no familiarity with either the grant application or manuscript submission process. We have addressed this need among our residents and new faculty by offering lectures and workshops dealing with these subjects.

**OGSP’s Interactive Workshop Series on Grant Writing**

Once a year we offer a grant writing workshop for our university investigators that is held one morning a week for 4 weeks. The first session provides an overview of the grant writing and submission process that introduces key grantsmanship concepts, such as writing to your audience (i.e., the reviewer). Subsequent sessions dissect the major sections of an NIH grant, which we have found is similar to most other grant applications, all the while emphasizing the need to write to the review criteria.

A few years ago, our workshop series underwent a major overhaul when NIH made substantial changes to the format of their grant applications. In addition to shortening the standard application from 25 pages to 13 pages (a 1-page Specific Aims plus a 12-page Research Strategy), NIH reorganized the format to more readily correspond with the review criteria. Thus, the original Research Design and Methods section, consisting of the Background, Significance, Preliminary Studies, and Methods, was turned into the Research Strategy composed of just three sections: Significance, Innovation, and Approach, with Preliminary Studies added in “where appropriate.”

The new application is therefore more of a marketing tool than ever before, which means we need to “sell” the solid science by writing a convincing application that grabs the reviewer’s attention. The concept of marketing oneself as an investigator, one’s laboratory as a unique environment, and one’s work as an eminently fundable venture is often eye-opening for both the novice and the seasoned grant applicant attending our workshop.

Another feature of our grant writing workshop is its interactive nature. Approximately half of each session is devoted to working in small groups of approximately five or six individuals, with each group hosted by a member of our editing team. Throughout the 4-week series this group concentrates on reviewing a Specific Aims page that has been developed by each workshop attendee. The editor provides a completely edited version for discussion, whereas other attendees offer constructive reviews from a more scientific perspective. At the conclusion of the workshop series, each attendee would have a fully reviewed and edited Specific Aims page, which basically represents a synopsis of the grant application.

This workshop series has been very popular and remains well attended throughout the 4-week period. We have also found that it facilitates collaborations among the attendees, who represent multiple UAMS colleges and departments, and often leads to future requests for OGSP services. In addition, our workshop has been added to the curriculum for certain programs at our university, such as the Clinical and Translational Sciences Certificate in Oncology fellowship program.

We try to accommodate as many as 25 attendees in our workshops, but we limit this number based on how many editors are available to lead each of the small breakout groups. The workshop series is not intended to replace the editing services provided by our office; rather, its goal is to increase the quality of the grants we receive for editing, and in this manner we believe it has been successful.

**Lecture on Manuscript Preparation**

Another main teaching tool provided by our office is a 1-hour lecture on manuscript preparation. Our primary audience is medical residents, many of whom have not yet authored and published a peer-reviewed scholarly piece. In fact, the concept of peer review may be an entirely new term for early-stage investigators. This straightforward lecture discusses issues of authorship, the main sections of a standard manuscript for a journal, and, finally, the steps involved in submission of a manuscript, including identifying target journals, the peer review process, and providing an appropriate response when asked for a resubmission.

Unlike our grant writing workshop series, which carries a fee of $250 per attendee, the manuscript lecture is provided at no cost to a department. In addition, in an effort to increase the number of publications submitted by our faculty, we provide any workshop attendee who co-authors a manuscript with a faculty member a free round of editing (approximately 10 hours) for that paper.

**COSTS INVOLVED**

Currently, OGSP bills at an hourly rate of $55. For departments in the College of Medicine, 75% of the total cost for a grant submission is covered by the Office of the Dean, substantially reducing the overall cost to the department. A typical grant application entails approximately 40 hours of an editor’s time, from start to finish, but the number of hours may vary considerably depending on the application guidelines (applications to the Department of Defense, for example, require an extensive amount of ancillary material in addition to the research plan). Other factors are involved, including whether the principal investigator needs assistance with the English language or if he or she is new to grant writing. The time involved represents substantive editing of very complex material, often with multiple iterations. Interestingly, we have found that the shorter NIH applications or the typically short (5-page) foundation grants do not necessarily require a shorter amount of editing time. A manuscript, on the other hand, may only require 10 to 20 hours of an editor’s time, as we have found that most investigators are more accus-
tomed to the guidelines and required style of manuscript writing. However, depending on the length and other factors, the time involved may easily be comparable to that of a grant application. Figure 2 illustrates OGSP production over the previous eight years.

Currently, we do not document the number of investigators who decline to use our services based on the fee schedule. However, in an effort to help all faculty members, we have developed a website with extensive information1 that contains links to funding sources, grantsmanship resources, grant application guidelines, and templates we have developed to assist in preparing a grant, as well as links to other shared resources on campus.

TRACKING SUCCESS RATES
Evaluating the success rate of OGSP has proven elusive. We have numerous testimonials provided by those we have helped indicating the value of our office, and we encourage investigators to provide only positive feedback to their department chairs and respective deans. However, we have yet to develop a tried and true system that objectively scores successes and failures. In addition, quality and productivity metrics used by other organizations that employ medical communicators, such as pharmaceutical and biotechnology companies,6 are not readily applicable to OGSP. Although a recent publication discussed the effect of editing on manuscript acceptance time,7 it is difficult to translate this type of evaluation to our work.

This is primarily due to the nature of the grant and manuscript submissions process at an academic health care center. For example, a grant application is likely to go through two submissions before it is funded. Often, an investigator will opt out of our services for the second submission, and we may never know whether or not the subsequent submission is funded. Another common scenario involves submitting a “failed” grant to another organization, which then proceeds to fund the grant. Again, if we are not involved in this process, or if the elapsed time to the final outcome is overly long, we may never know the final outcome.

When time and scheduling do allow, we try to obtain this type of information by using NIH RePORTER, a database that is updated weekly and lists those grants funded by NIH.8 Although this does not capture non-NIH submissions, we have found it helpful for tracking down a large proportion of the grants edited by OGSP.

Similarly, a manuscript is typically submitted, reviewed, revised, and then accepted with revisions. If our office is not involved in the revision process, we have no information about the ultimate outcome. Additionally, if the manuscript is rejected by a journal, an investigator may resubmit it to an alternate journal. Again, if we are not included in the process, we may not learn if the manuscript was ultimately accepted for publication. And, unlike at a pharmaceutical company, where one department will oversee production of a specific type of regulatory document and another will oversee publications, there is no overarching organization within our university that oversees the manuscript submission enterprise.

Instead, we depend upon investigator follow-up to let us know of a successful publication, and, in part because of the elapsed time involved, this is not always a reliable method. When time allows, we search the online PubMed database9 that comprises more than 22 million citations for the biomedical literature, to determine whether or not a manuscript has been published in an indexed journal. One caveat when using PubMed for this purpose, however, is that multiple iterations of a manuscript may result in a substantially revised title. This can make it difficult to identify those publications edited by our office, particularly if full-text content is not readily available to us.

Nonetheless, we believe that if the ultimate outcome is a successful grant application or publication and if our office has worked on any version of it, then it should be counted among our successes. We are developing a database that will have unique identifiers (eg, the investigator’s e-mail address and the assigned project number; other potential identifiers, such as the grant title, are likely to change, even before the first submission), enabling us to more accurately track a grant application’s progress. These identifiers will then be linked to the OGSP database. In this way, we will have confirmation of a grant submission and will be able to be alerted when it has been rejected, scored, or funded.

We are also developing a customer survey by using SurveyMonkey (www.surveymonkey.com), which will automatically distribute a simple 1-page questionnaire electronically to our investigators when a project (grant or manuscript) has been completed by one of our editors. The software will automatically update survey results, allowing our office to evaluate investigator feedback over the long term. We will also be able to track the progress of a grant application or manuscript by automatically redistributing the survey to investigators on a 6-month cycle. We hope that the combined use of SurveyMonkey with our revamped database will allow us to more accurately track success and failure rates as well as investigator opinion of our editing efforts.
FUTURE DIRECTIONS
The fields of science and medicine are never stagnant, and, as a result, neither is our office. We keep current with changes at the NIH, and with new funding opportunities through the extensive NIH website (www.nih.gov) as well as Grants.gov (www.grants.gov). Because we are all AMWA members, we can also glean important information from the AMWA e-mail discussion groups, the AMWA Journal, and AMWA meetings. Finally, we hope to take portions of our workshop series on the road by submitting certain sessions as courses to upcoming scientific academy meetings. The success of this venture remains to be seen, but workshop attendees at our institution have suggested the idea is worth pursuing.

CONCLUSION
OGSP provides a mentoring experience to investigators seeking funding of their research and/or publication in peer-reviewed journals. In addition to substantive editing services, members of our office provide interactive workshops and lectures that instruct investigators in all aspect of grantsmanship and the peer-review process. Certain metrics are being developed to objectively measure our success rate with both of these endeavors (funding, publication), but for now we rely on the positive feedback we have received from the many investigators whom we have helped. We believe that the mentoring provided by our office results in an investigator/editor relationship that ultimately produces high-quality documents and that recognition of the importance of this relationship during any editing job can be applied to others in the field of scientific or medical communication.

Author disclosure: The author notes that she has no commercial interests that may pose a conflict of interest with this article.

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References
ABSTRACT
The endocrine system helps to maintain and control a wide range of important body functions. These functions include the regulation of energy levels, control of reproductive function, regulation of growth and development, maintenance of homeostasis, and coordination of the body’s response to stress.

The endocrine system consists of a network of organs that are located in different parts of the body and are not anatomically connected. These organs, called endocrine glands, are the hypothalamus, pituitary, ovaries, testes, adrenal glands, pancreas, thyroid gland, parathyroid glands, pineal gland, and thymus. Because they are not anatomically connected, the endocrine glands communicate with each other through chemicals called hormones. Each endocrine gland makes different hormones that are released into the bloodstream or interstitial space and exert their effects on distant or neighboring target organs. The target organs are other endocrine glands and nonendocrine organs.

An understanding of the endocrine system is important to medical writers because the endocrine system has wide-ranging physiologic effects in various disease states. In this first of a two-part series, we introduce the endocrine system, discuss the anatomy of the endocrine glands, and describe the hormones that these glands produce. We then present some basic concepts in endocrinology, including the different types of hormones, mechanisms of hormone action, and control of hormone levels. The physiology of the endocrine system will be addressed in Part 2.

The endocrine system is made up of several endocrine glands that are located in different parts of the human body (Figure 1). Unlike other body systems, such as the digestive and cardiovascular systems, the endocrine system does not consist of organs that are anatomically connected. Instead, the endocrine glands communicate with each other through chemicals called hormones. Hormones are manufactured and stored in the endocrine glands and are released from these glands to exert their effects on neighboring or distant target organs. These target organs can be other endocrine glands or nonendocrine organs such as the liver, kidneys, bone, and muscle.

Endocrine glands are sometimes called “ductless glands” because they secrete their products (hormones) directly into the blood or into the interstitial space. Endocrine glands are therefore different from exocrine glands, which secrete their product into ducts that lead directly into the external environment (eg, sweat glands and mammary glands). Some organs, such as the pancreas, are both endocrine and exocrine organs.

The endocrine system works with other organs and body systems, including the kidneys, the nervous system, the immune system, the reproductive system, and the digestive system, to help maintain homeostasis and control many body functions.

Figure 1. Anatomical locations of endocrine glands. (Reprinted with permission. Copyright 1995-2012. American Medical Association. All Rights Reserved.)
it is about the size of an almond. The hypothalamus is composed of discrete clusters of cells called nuclei that have specific functions. Some nuclei produce and secrete hormones that start and stop the production and release of pituitary gland hormones. These hormones are transported from the hypothalamus to the anterior pituitary gland through a special set of blood vessels called the hypophyseal portal system.

Other hormones produced in the hypothalamus are transported through long axons of the nuclei to the posterior pituitary gland.

**Pituitary Gland**

The pituitary gland (also known as the hypophysis) is located just below the hypothalamus in a bony hollow called the sella turcica. In adults, the pituitary gland is about the size of a pea. The pituitary gland is often referred to as the “master gland” because of its effects on other organs. It is divided into two parts, the front (anterior) and back (posterior). The anterior pituitary gland consists of five distinct cell types that produce and store protein and peptide hormones:

<table>
<thead>
<tr>
<th>Gland</th>
<th>Hormones Produced</th>
<th>Roles</th>
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<tbody>
<tr>
<td>Hypothalamus</td>
<td>Corticotropin-releasing hormone</td>
<td>Control of production and release of pituitary hormones</td>
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<td>Thyrotropin-releasing hormone</td>
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<td>Gonadotropin-releasing hormone</td>
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<td>Somatostatin</td>
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<td>Hypothalamus and posterior</td>
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<td>pituitary</td>
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<td>Control of water resorption by the kidneys</td>
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<td>Anterior pituitary</td>
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<td>Control of cortisol release from the adrenal cortex</td>
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<td>Thyrotropin</td>
<td>Control of thyroid hormone release from the thyroid gland</td>
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<td>Luteinizing hormone</td>
<td>Control of reproductive function, including estrogen and progesterone production in the ovaries and testosterone production in the testes</td>
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<td>Follicle-stimulating hormone</td>
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<td>Growth hormone</td>
<td>Regulation of growth and development and energy metabolism</td>
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<td>Prolactin</td>
<td>Stimulation of milk production</td>
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<td>Ovaries</td>
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<td>Testes</td>
<td>Testosterone</td>
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<td>Pancreas</td>
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<td>Control of glucose levels and energy metabolism</td>
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<td>Glucagon</td>
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<td>Adrenal cortex</td>
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<td>Coordination of responses to stress, glucose regulation, and immune system reactions</td>
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<td>Aldosterone</td>
<td>Control of blood volume and kidney function (sodium and water retention, potassium excretion)</td>
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<td>Adrenal medulla</td>
<td>Catecholamines: epinephrine (adrenaline) and norepinephrine (noradrenaline)</td>
<td>Coordination of response to stress (fight or flight)</td>
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<td>Thyroid</td>
<td>Triiodothyronine</td>
<td>Regulation of growth and development, metabolism, body temperature, and oxygen consumption</td>
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<td>Parathyroid</td>
<td>Parathyroid hormone</td>
<td>Control of calcium and phosphate levels</td>
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<tr>
<td>Pineal</td>
<td>Melatonin</td>
<td>Control of sleep-wake cycles, hibernation, and seasonal breeding</td>
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<tr>
<td>Thymus</td>
<td>Humoral factors</td>
<td>Development of the lymph system</td>
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*a Produced in the hypothalamus but released from the posterior pituitary.*

**Table 1. Endocrine Glands, Hormones, and Their Roles**
1. Corticotrophs—corticotropin (formerly called adrenocorticotrophic hormone [ACTH])
2. Somatotrophs—growth hormone
3. Lactotrophs—prolactin
4. Thyrotrophs—thyrotropin (formerly called thyroid-stimulating hormone [TSH])
5. Gonadotrophs—luteinizing hormone (LH) and follicle-stimulating hormone (FSH)

The posterior pituitary gland stores and secretes two hormones that are produced in the hypothalamus: oxytocin and antidiuretic hormone (ADH), which is also called arginine vasopressin (AVP).

Ovaries
The ovaries are female reproductive endocrine organs. They are a pair of oval structures that are each about the size of a large olive and are located in the pelvic cavity. Ovaries are considered to be both endocrine organs and gonads (organs that make gametes, which are specialized cells for reproduction). As endocrine organs, ovaries have granulosa cells that produce estrogens and progesterone, which help control reproductive function in women. As gonads, the ovaries produce ova, or eggs (the gametes of females), which are also stored in the ovaries and undergo maturation there.

Testes
The testes are male reproductive endocrine organs. They are a pair of ellipsoid organs within the scrotum. Each testis has an average volume of 18 cm³. Like ovaries, testes are both gonads and endocrine organs. Sperm (the gametes of males) are produced and stored and undergo maturation in the Sertoli cells of the testes. The testes also serve as endocrine organs, with the Leydig cells producing androgens (including testosterone), which help control reproductive function in males.

Pancreas
The pancreas is located behind the stomach and duodenum. Special cells within the pancreas, called the islets of Langerhans, produce insulin, which maintains healthy blood glucose levels. When glucose levels in the blood are too high, insulin stimulates the uptake of glucose by muscle, fat, and liver cells, thus lowering blood glucose levels. The pancreas produces another hormone, glucagon, which is secreted when blood glucose levels are too low and causes glucose to be released from the liver. In addition to having an endocrine function, the pancreas has an exocrine function: it secretes pancreatic juice through the pancreatic duct into the small intestine, where the pancreatic juice (which contains digestive enzymes) aids in digestion.

Adrenal Glands
The adrenal glands are a pair of endocrine organs located on the top of each kidney. Adrenal glands have two distinct endocrine regions. The outer part of the gland, the cortex, produces steroid hormones, including aldosterone, androgens, and cortisol. Aldosterone is involved in the control of blood volume and kidney function. Cortisol helps the body respond to stress. The inner part of the adrenal gland, the medulla, produces the catecholamines epinephrine and norepinephrine. These two hormones are released in response to stress and help mediate the fight-or-flight reaction.

Thyroid Gland
The thyroid gland is a butterfly-shaped organ with two lobes. It is located in the neck in front of the trachea and below the Adam’s apple. Hormones produced by the thyroid gland, namely triiodothyronine (T₃) and thyroxine (T₄), help control metabolism and have roles in growth and development. The thyroid gland also produces calcitonin, which is important for calcium regulation.

Parathyroid Glands
The parathyroid glands are small endocrine organs that are located behind the thyroid gland. Humans usually have four parathyroid glands, each about the size of a grain of rice, with two located on the left lobe of the thyroid gland and two on the right. These glands help control calcium and phosphate levels and are also important for normal bone development. The parathyroid glands produce and secrete parathyroid hormone (PTH), which stimulates calcium release from bone.

Pineal Gland
The pineal gland, which is about the size of a pea, is located in the brain behind the thalamus. This gland is sometimes called the “third eye” because of its role in regulating sleep-wake cycles and seasonal functions. The pineal gland produces and secretes melatonin, which has a role in modulating circadian rhythms.

BASIC CONCEPTS IN ENDOCRINOLOGY
Types of Hormones
There are three main classes of hormones: protein and peptide hormones, steroid hormones, and monoamine hormones. The majority of hormones are proteins or peptides, which are composed of 3 to 200 amino acids. Protein and peptide hormones are made in the hypothalamus, pituitary gland, adrenal medulla, and pancreas. Examples of these hormones are growth hormone and insulin. Some protein hormones also have a carbohydrate component and are called glycoproteins. Examples of glycoproteins are the pituitary hormones LH and FSH. Some protein and peptide hormones are synthesized as larger molecules called prohormones; a prohormone is divided to produce one or more active hormones. For example, the pituitary hormones corticotropin, beta-endorphin (an opioid), and melanocyte-stim-
ulating hormone (MSH) are all derived from a single prohormone called pro-opiomelanocortin (POMC).

Steroid or lipid hormones are derived from cholesterol. They are made in the adrenal cortex, ovaries, testes, and placenta. Examples of steroid hormones are cortisol, estrogen, and testosterone.

Monoamine hormones are derived from the amino acids tyrosine and tryptophan. Examples of these hormones, which are made in the adrenal medulla and the thyroid gland, are epinephrine, norepinephrine, and the thyroid hormones T₃ and T₄.

**Mechanism of Action of Hormones**

Hormone actions can be classified into three types:

1. **Endocrine**—hormones enter the bloodstream and act on distant organs.
2. **Paracrine**—hormones are released into the interstitial space and act on neighboring cells.
3. **Autocrine**—hormones act on the same cells that produce them.

Hormones exert their effects on their target organs through receptors. Target organs have receptors that are specific for a particular hormone. For example, the thyroid gland has receptors for the pituitary hormone thyrotropin, but it does not have receptors for other pituitary hormones. There are two types of receptors: cell surface receptors and intracellular receptors. Protein and peptide hormones are too large to cross the cell membrane; therefore, they bind to receptors on the outside of the cell surface. When a protein or peptide hormone binds to its receptor, a hormone-receptor complex is formed. The complex initiates a cascade of intracellular events, resulting in a specific biologic response, such as the production of another hormone, enzyme, or other chemical.

Steroid and thyroid hormones are much smaller than protein and peptide hormones and can cross the cell membrane and bind to intracellular receptors. This hormone-receptor complex then binds to DNA, causing activation or repression of gene expression and, ultimately, a specific biological response.

**Control of Hormone Levels**

The amount of a particular hormone circulating in the blood is very small and usually has to be maintained within narrow limits. For example, in the bloodstream the concentration of the pituitary hormone corticotropin ranges from 10 to 80 ng/mL, and the concentration of cortisol ranges from 5 to 23 µg/dL.

The endocrine system and the levels of circulating hormones are partly controlled by the nervous system and are partly self-controlled through mechanisms by which one hormone stimulates or inhibits the release of another hormone. A hormone that stimulates the release of another hormone is called a tropic hormone.

Nervous system control of the endocrine system is mediated mainly through an area of the brain called the hypothalamus. The hypothalamus is a neuroendocrine gland that receives stimuli from the central and peripheral nervous systems and produces hormones called neuropeptides or releasing hormones in response to these signals. These hormones then stimulate or inhibit the release of hormones from other endocrine glands, in particular the pituitary gland.

Hormonal control of the endocrine system is mediated through negative and positive feedback mechanisms (Figure 2). These are mechanisms whereby the concentration of one hormone in the blood can control the production and release of another hormone. For example, the pituitary hormone thyrotropin stimulates the release of thyroid hormones (T₃ and T₄) from the thyroid gland. When the level of thyroid hormones in the blood is too low, the pituitary gland produces more thyrotropin to stimulate the production and release of T₃ and T₄. However, if too much thyrotropin is produced, the levels of T₃ and T₄ will become too high. The pituitary gland detects the high levels of T₃ and T₄ and responds by decreasing the production of thyrotropin, resulting in a corresponding decrease in the production and release of T₃ and T₄. This mechanism is an example of negative feedback.

Sometimes, increasingly high levels of a hormone are required. For example, a surge of the pituitary hormone LH is required during the menstrual cycle for ovulation. LH stimulates the production of estrogen in the ovaries, and these higher levels of estrogen stimulate the pituitary gland to release more LH.

**Figure 2.** Negative and positive feedback. **A.** In this example of negative feedback, the pituitary gland produces thyrotropin, which stimulates the release of thyroid hormone from the thyroid gland. When levels of thyroid hormone become too high, they act on the pituitary gland to inhibit the release of thyrotropin. **B.** In this example of positive feedback, the pituitary gland produces luteinizing hormone (LH), which stimulates the production of estradiol, an estrogen, from the ovaries. Estradiol acts on the pituitary gland to stimulate the production of LH, which in turn stimulates the production of even more estradiol from the ovaries.
produce more LH, thus triggering the surge of LH that is required for ovulation. This mechanism is an example of positive feedback.

**SUMMARY**
The endocrine system is an important physiologic system that has a vital role in maintaining and controlling a wide range of body functions. The endocrine system is a network of anatomically distinct organs (glands) that communicate with each other through chemical messengers called hormones. Endocrine glands are located in different parts of the body, including the brain (hypothalamus, pituitary gland, and pineal gland); neck (thyroid and parathyroid); abdomen (pancreas and adrenal glands); and pelvis (ovaries and testes). The endocrine glands vary in size, and each gland has specialized cell types that produce and secrete specific hormones. The hormones can be proteins, peptides, steroids, or monoamines. These hormones circulate in the bloodstream in very low concentrations. Hormones exert their effects on endocrine and nonendocrine target organs by binding to the cell surface or intracellular receptors. Hormone production and release are controlled by the nervous system and by hormonal feedback mechanisms. The endocrine system thus works with other body systems to control and coordinate many physiologic processes, including reproductive function, growth and development, maintenance of homeostasis, and responses to stress.

**Author disclosure:** The authors note that they have no commercial associations that may pose a conflict of interest in relation to this article.

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**Glossary**

- **autocrine**—A substance that is secreted by a cell and acts on surface receptors of the same cell.
- **endocrine**—A substance that is secreted by a cell and is distributed in the body through the bloodstream.
- **endocrine gland**—A ductless gland that produces hormones and releases them into the circulation (eg, pituitary gland, ovaries, pancreas).
- **endocrine system**—An integrated network of multiple organs that release hormones that exert their effect on neighboring or distant target cells.
- **homeostasis**—Maintenance of a constant internal environment.
- **hormone**—A chemical that is released by an endocrine gland and affects cells in an organ in another part of the body (eg, insulin, growth hormone, estrogen).
- **interstitial space**—The fluid-filled space surrounding cells in a particular tissue.
- **neuroendocrine**—A cell type that secretes hormone into the bloodstream in response to a neural stimulus (eg, the hypothalamus is a neuroendocrine gland).
- **neuropeptide**—A peptide hormone that is produced in the hypothalamus and transported to and released from the posterior pituitary gland.
- **paracrine**—A substance that is secreted by a cell and acts on adjacent cells.
- **prohormone**—A large molecule (usually a protein or peptide) that is a precursor to a hormone; prohormones have minimal biological activity and require further processing to become active.
- **receptor**—A structure on the cell surface or within a cell that recognizes a particular hormone and causes a specific biological response when that hormone binds to it; the biological response can cause an upregulatory or downregulatory effect on the cell.
- **releasing hormone**—A hormone that is produced in the hypothalamus and controls the release of other hormones from the anterior pituitary gland.
- **target organ**—An organ with cells that have specific receptors for a hormone and show a biological response when the hormone is present and binds to the receptor.
- **tropic hormone**—A hormone that stimulates the release of another hormone.

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**Recommended Reading**


**Erratum:** The state abbreviation for Kansas was incorrect in Figure 2 on page 58 and in a thumbnail on the cover of a recent issue of the Journal (Volume 27, No. 2). The correct abbreviation is KS.
Snapshots of the 2012 AMWA Annual Conference

AMWA thanks the following companies for their generous support of the 2012 AMWA Annual Conference.

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Hosts of the 2012 Annual Conference: the Northern California and Pacific Southwest Chapters.

Susan Aiello, DVM, ELS, received AMWA’s highest honor, the Swanberg Distinguished Service Award. (Listen to Susan’s presentation, complete with slides, in Conference Coverage, an online exclusive.)

The conference provided numerous opportunities for networking, including receptions, a networking luncheon, and the business meeting luncheon.

Barbara Snyder, MA, 2011-2012 AMWA President, passes the gavel to Douglas Haneline, PhD, 2012-2013 AMWA President. (See Doug’s inaugural Presidential Address on page 183.)

Photos by D. Durgin Photography
Q & A to E3: A Must-Read for Regulatory Writers*

By Nancy R. Katz, PhD
President, Illyria Consulting Group, Inc., Soda Springs, CA

Why a Q & A? The Q & A to E3 was developed to clarify the original guideline and, especially, to align it with the Common Technical Document (CTD).

E3 and the CTD: The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was launched in 1990. Its mission: to achieve “greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration” (www.ich.org). Its ultimate goal: to facilitate the development of safe and efficacious medicines for human use.

To support these objectives, ICH developed a series of guidelines. ICH E3, finalized in 1995 and adopted by 1996 in all three ICH regions (European Union, Japan, and the United States), plays a crucial role in the expedited development of new medicines. By standardizing criteria for a clinical study report (CSR), a document describing the conduct and results of a clinical trial of an investigational drug in human subjects, E3 enables submission of the same CSR to regulatory bodies in all three ICH regions, obviating the need for submission of a separate CSR to each region.

The CTD, implemented in 2000, plays yet another crucial role, allowing assembly of all information related to an investigational drug into one common document. In July 2003, the CTD became the mandatory format for new drug applications in the European Union and Japan; it is now the strongly recommended format for a New Drug Application (NDA) submitted to the US Food and Drug Administration (FDA). Importantly, current technology allows electronic submission of the CTD (hence: the “eCTD”), a practice encouraged by many regulatory authorities.

Conflict/Delay/Medical Writer Action: CSRs written according to ICH E3 criteria are mandatory portions of a CTD-based application asking for approval of a new medicinal drug. On the surface, some requirements of E3 appear to conflict with some requirements of the CTD, particularly an eCTD. Within the biopharmaceutical industry, various individuals have interpreted E3 as a rigid template and refused to modify it. Other individuals, however, have advocated for modification of E3, although not always a consistent modification. The incompatible interpretations of E3 resulted in lengthy and often vituperative discussions within the walls of biotechnology and pharmaceutical companies. Unhappily, these discussions resulted in delayed writing of CSRs and delayed submission of CTD-based applications.

Under the auspices of the Drug Information Association (DIA), a global group of medical writers (a subgroup of the DIA Medical Writing Special Interest Area Community) identified conflicts between the requirements of E3 and those of the CTD, suggested ways to resolve them, and presented the findings to FDA advisors. Recognizing that industry strife could result in delayed delivery of needed medicines, the FDA agreed to support a series of clarifying Q & A to E3. In June 2011, the global medical writing group developed and submitted a concept paper justifying this need to the ICH Steering Committee. In turn, the ICH Steering Committee convened an International Working Group (IWG) of medical writers who used the concept paper to develop the series of clarifying Q & As. One year later, on June 7, 2012, Justina Molzon, chair of the ICH Steering Committee, signed the finalized Q &A document to help create efficient, compliant, and scientifically accurate CSRs.

The Q & A document includes several key points (Table 1). The take-home message is that E3 is a guideline, not a rigid template. Intelligent adaptations of E3 are permissible, especially those that allow electronic submission of a CTD-based drug application.

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Table 1. Key Points in the Q & A Document

<table>
<thead>
<tr>
<th>ICH E3 as a template or guideline</th>
<th>The ICH E3 is a guideline, not a rigid template, and flexibility is inherent in its use. Modifications and adaptations to the structure that lead to better display and communication of information are encouraged. If particular types of information or topics are not addressed in E3 or their location is not specified (e.g., pharmacokinetic results), these results may be placed in appropriately identified subsections.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of a synopsis</td>
<td>The synopsis should be written to be used as a stand-alone document within the CTD. Complex or large and important studies may require a synopsis longer than the 3 pages specified in ICH E3.</td>
</tr>
<tr>
<td>Including documents available in the Trial Master File (TMF) as appendices to a CSR</td>
<td>Since the TMF is not submitted in the marketing application, the CSR appendices should contain all documentation needed to review the CSR. Supportive documents (investigator CVs, ethics committee approvals, informed consent forms, etc) should generally not be included in the CSR appendices, but should be available promptly if requested by a regulatory authority.</td>
</tr>
<tr>
<td>Submitting data for topics not specifically covered by ICH E3</td>
<td>It is appropriate to create new headings in the CSR and new appendices for these topics such as pharmacokinetics, pharmacodynamics, pharmacogenomics, biomarkers, devices.</td>
</tr>
<tr>
<td>Including deaths in Section 12.3.1.1 (Deaths) and 12.3.1.2 (Other Serious Adverse Events)</td>
<td>Any death should be included in Section 12.3.1.1 and will also appear in Section 12.3.1.2 as an “other serious adverse event” with a fatal outcome.</td>
</tr>
<tr>
<td>Inclusion of example AE table provided in Section 12.2.2</td>
<td>The example table provided in Section 12.2.2 is intended to be included as a Section 14 table (not in the body of the CSR). The in-text table should compare relatively common AEs across treatment and control groups.</td>
</tr>
<tr>
<td>Difference between a “protocol deviation,” an “important protocol deviation,” and a “protocol violation”</td>
<td>A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol. Important protocol deviations are a subset of protocol deviations that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject’s rights, safety, or well-being. Protocol violation and important protocol deviation are sometimes used interchangeably to refer to a significant departure from protocol requirements. To avoid confusion over terminology, sponsors are encouraged to replace the phrase “protocol violation” in ICH E3 Annex IVa with “protocol deviation” or another descriptor, provided that the information presented is generally consistent with the definition of protocol violation provided above.</td>
</tr>
</tbody>
</table>

Note: The DIA Medical Writing Special Interest Area Community, known as the E3 Committee, consisted of Nancy Katz (chair), Sybille Eibert, Julie Ely, Helle Gaulevlewska, Sandy Hecker, Barbara Kamm, Evelyn Kopke, Justina Molzon, Christopher Preston, Jean Soul-Lawton, Mary G. Stewart, Therese Stickler, Henriette Totka-Rockwell, Sue Wilson, and Linda Wood.

The E3 Committee is deeply grateful for the invaluable feedback and support of FDA advisors Howard Chazin, MD; Gary Gensinger; Virginia Ventura Hussong; Robert Temple, MD; and Ellis Unger, MD; and of the many FDA clinical reviewers who participated in this process.
By Michelle Eby, PharmD, CCRP
Dr Pincock’s role as a senior official on the Food and Drug Administration’s (FDA) Safety and Risk Communication Team (SRCT) is to inform the public on matters about new and emerging potential safety issues that occur after drugs are marketed. In addition to its regulatory duties, the FDA’s mission is to provide timely, understandable, relevant, and actionable information. This responsibility entails providing health care professionals and their patients with information to make the best individual medical treatment decisions. Dr Pincock outlined the FDA’s framework to accomplish this goal and illustrated the Agency’s use of best practices for risk communication, along with a description of the FDA’s attempts to evaluate the effectiveness of its risk communication program. In particular, she addressed the importance of maintaining an ongoing rapport with the use of frequent advisories on up-to-date safety information. This open-ended approach seeks to educate the public on the dynamic nature of a drug’s risks and benefits.

Dr Pincock discussed product labeling or package inserts as the legally required product information for all prescription medication as FDA’s principal tool for communicating established risks. When a side effect or warning is added to the product label or package insert, there is a high standard of evidence. In contrast to these established risks, emerging risks have greater uncertainty and, therefore, may not yet be included in the product label.

Before 2010, the FDA used a variety of methods to communicate emerging drug safety risks. In January 2010, the FDA established the SRCT to communicate emerging risks using a mechanism called Drug Safety Communications (DSCs).

When drugs are studied to gain FDA approval, finite numbers of patients who satisfy strict eligibility criteria are enrolled in clinical trials. After FDA approval, unknown risks may emerge because these same drugs may be taken by a different population or for an entirely different disease. Once outside the clinical trial setting, the likelihood of an adverse event may actually increase. Adverse events are reported to the FDA via MedWatch forms and entered into the Adverse Event Reporting System (AERS) database. In turn, FDA drug safety experts review the AERS database to evaluate and assess safety signals for emerging risks. FDA’s experts similarly review the medical literature for early adverse events.

In order to provide a fair and balanced approach when writing DSCs, FDA experts look at the benefits that patients receive from the medication and evaluate the benefit-to-risk ratio. Patients do not necessarily need to discontinue a valuable therapy in light of updated safety information. The primary purpose of the DSC is to help individuals make an informed decision about their medication.

Dr Pincock listed several factors that affect the benefit-to-risk ratio when writing DSCs: the seriousness of the adverse event relative to the benefits of the overall treatment, the strength of the evidence of a causal relationship, the potential for preventing or mitigating the risk, and the availability of alternative therapies. For example, if no other drug is available to treat a serious disease, the acceptance of risk may be higher; the FDA takes such factors into consideration when writing the DSC.

Other challenges with developing DSCs include writing for multiple audiences, communicating uncertainty, and working within legal and regulatory constraints. For example, the FDA may not be able to recommend one drug over another drug because it must provide unbiased information.

Early in the DSC development process, FDA experts discuss whether and when to communicate, and which communication tool to use. They look at safety signals and review additional data when needed. Before withdrawing a drug from the market or changing the label or package insert, the FDA may issue a DSC (Figure 1). In general, DSCs communicate issues affecting a large number of patients, potentially serious or life-threatening adverse events, new contraindications or warnings, a previously uncharacterized drug-drug or drug-disease interaction, or a medication error that could result in a serious or life-threatening adverse reaction. For example, in July 2012, the FDA issued a DSC regarding the risk of seizures in patients receiving Ampyra, a drug for multiple sclerosis. Seizures were a known side effect of Ampyra; however, the DSC warned that the risk of seizures was greater for patients with reduced renal function. Prescribers were advised to check patients’ renal function before starting the drug.

Figure 1. Regulatory decision-making. (Figure courtesy of the Food and Drug Administration.)
DSC’s standard format entails tiered messaging so that different audiences can access information relevant to them. The Safety Announcement section, the first several paragraphs, is a summary of the DSC. It is written in consumer-friendly language, also known as plain language. According to Dr Pincock, “The introductory paragraph is key and serves to hook in readers.” The blue box on the side gives facts about the drug, such as benefits and number of patients who have used it (if known). The next section is Additional Information for Patients, which provides helpful information written in plain language for patients. The Additional Information for Healthcare Professionals section provides more descriptive medical and technical information about the safety issue. The Data Summary section is the most detailed and may include case reports, epidemiologic, methodologic, and statistical information.

The goal of DSCs is to explain the issue as clearly as possible and anticipate what the public needs to know. Persuasive language is used to convey new safety information to health care professionals who, in turn, will advise or monitor patients. Patients are told to take specific actions to minimize harm and maximize benefit.

The FDA gauges the effectiveness of DSCs by using web analytics, media monitoring, and public feedback. Web analytics measures how the message spreads online and is calculated as the total web posts per day. Major dissemination occurs within 1 to 2 weeks after the DSC posting. Diffusion is the breakdown of media types used to spread the message. The diversity of media increases the likelihood a message will be adopted. Duration, or the length of time the message receives significant online activity, is determined by the number of days the topic generates web posts after launch. The FDA also coordinates focus groups to solicit feedback from various stakeholders, including health care professionals and patients.

The FDA continues to evaluate and improve its communication effectiveness, with the purpose to provide actionable information for health care professionals and patients. Aside from fostering public trust and confidence, according to Dr Pincock, “The FDA’s overarching goal is to ensure that the right people get the right message at the right time.”

Michelle Eby is a Consumer Safety Officer for the Food and Drug Administration, Silver Spring, MD.

Don’ts of Prescription Drug Advertising
• Don’t frame or omit risk completely or partially.
  – Risk information must be provided in promotional materials that make product claims, and that information should include contraindications, warnings, precautions, and pertinent adverse events. “For example, there are several drug products you might be aware of that have an adverse reaction of weight loss. If you present that in your promotional or branded piece by saying that, in addition, you can lose weight while you’re on this product, that is really framing something that is a risk as a benefit, and that does violate the regulations,” explained Dr Hubbard.

• Don’t minimize risk.
  – Examples of minimizing risk include omitting material information about a risk described in the approved labeling, including non-risk information in a risk section, or vice versa, listing risk information as a benefit, and inappropriate presentation of risk through framing, layout or prominence, and sequencing.
  – Sequencing means that the most serious risks should be presented first.
• Don’t use misleading characterization, which is when indications are broadened.
  – Dr Hubbard described this as implying a drug to be useful in a broader population of patients or disease states than has been demonstrated.
  – Broadening also includes failing to disclose the full indication, including limitations.
• Don’t overstate efficacy by suggesting or representing the drug to be more efficacious than has been demonstrated.
  – Overstating efficacy can also occur by guaranteeing efficacy, claiming a faster onset of action, or making claims about survival or long-term outcome.
• Don’t make superiority claims, which are drug comparisons that represent or suggest that a drug is safer or more effective than another drug, whether implied or direct.
  – The standard of evidence for superiority claims is a head-to-head clinical trial.
  – Generic medications must demonstrate bioequivalence but cannot make a superiority claim without the results of a head-to-head trial.
• Don’t make a misleading mechanism of action claim, which could be suggesting a greater understanding of the mechanism of action than actually exists.
• Other don’ts of promotion and advertising are omitting or minimizing a drug’s prescription status, promoting unapproved uses, using unsubstantiated convenience claims, and failing to submit the promotional material at the time of first use.

Dos of Prescription Drug Advertising
• Review and apply the federal Food, Drug, and Cosmetic Act and the Code of Federal Regulations.
• Review guidances, enforcement actions, OPDP’s website, and the approved PI.
  – Be sure to look over competitors’ PIs and complaints that have been filed about promotional materials for relevant drugs.
• Remember to meet the standard for substantial evidence.
  – The regulatory definition for substantial evidence for efficacy claims is generally two adequate, well-controlled clinical trials.
  – Substantial evidence is required to support claims in the PI, and the same level of evidence is required to support claims in promotional materials. It is possible to substantiate claims outside of the PI.
• Communicate with the OPDP as needed.
  – The OPDP offers information on its website, through its guidances, and through outreach initiatives that include conferences, trade press, and webinars.
  – The quarterly webinars hosted by the OPDP are a forum to look at enforcements and ask questions.
• Seek advisory letters from the OPDP, which are a mechanism to get the OPDP’s opinion about marketing campaigns and claims before they are publicly disseminated.
  – This is voluntary, confidential, and a subpart H exception. Subpart H refers to the FDA’s Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses, which was enacted in 2002.
• Do communicate with OPDP enforcement letters.
  – In contrast to advisory letters from the OPDP, OPDP enforcement letters pertain to pieces in the public domain and are public letters.
  – Enforcement letters can be untitled, or, for more egregious or repeat violations, a warning letter.
  – The impact of these letters is the expectation of immediate cessation of violative claims and presentations.
  – Those who receive a warning letter are expected to respond with a corrective message.

Responding to Unsolicited Requests for Off-Label Information
Dr Hubbard explained how to respond to unsolicited requests for off-label information, which are defined as requests initiated by persons or entities completely independent of the relevant firm and not prompted in any way by a manufacturer or its representatives. These requests can be nonpublic, which are directed privately to a firm through a one-on-one communication approach, or public, which are made in a public forum. The FDA’s policy is that, regardless of the type of request (nonpublic or public), if a firm chooses to respond, it should send the response as a private, one-on-one communication only to the specific individual who requested the information.

For nonpublic requests, the response should be tailored to answer only the specific question asked, and the information provided must be truthful, nonmisleading, accurate, balanced, scientific, not promotional in nature, and generated by medical or scientific personnel. Responses should be accompanied by the FDA-required labeling.

Prominent statements in the response should explain that the product has not been approved or cleared by the FDA for the use addressed; disclose the FDA-approved indications; provide all important safety information, including any boxed warning; and provide a complete list of references for all of the information. After sending a response, a firm should keep records of the nature of the request for information, including the name, address, and affiliation of the requestor; the information provided to the requestor; and any follow-up inquiries or questions from the requestor.

Firms should only respond to a public unsolicited request when it is about their own product and not solely about a competitor’s product. The response should be limited to providing contact information for the firm, and it should not include any off-label information. This approach allows individuals to follow-up independently through a nonpublic communication. When representatives provide public responses, they must clearly disclose their relationship with the firm. Their responses should not be promotional.

Kathy Boltz is a freelance medical writer (kathybphd.com) in Phoenix, AZ.
biomedical writing online

Find out more at usciences.edu/biomedicalwriting.

Questions? Email us at biomedwriting@usciences.edu.

USciences
University of the Sciences

Where healthcare and science converge.
Every freelance I know works crazy hours.
How do you make time for yourself?

A - It is so true that we do work crazy hours and most projects come in with immediate start-up, rather than being scheduled ahead of time. I have only one client who schedules projects up to 2 months in advance as he is setting up Advisory Board meetings across the country. Others call and ask “Are you available for the next XX days or weeks?” or, “What does your schedule look like?”

There are two of us in our business, and we try to juggle projects and deadlines to take a long 3- or 4-day weekend (either away or at home) at least once each quarter. We also try to escape winter for a week but that seems to fall by the wayside most years.

Because we live in a remote area (no neighbors), we have to make a real effort to drive to the nearby town to keep up local friendships. We are both active in our church, usher four times a year for the local theater group, and are members of several clubs/groups. I am in a garden club that meets once a month and also volunteer at a local nursing home (playing bingo with the residents). Richard is very active in Boy Scouts, having 5 or 6 evening or Saturday meetings a month (Once an Eagle Scout, always an Eagle Scout!). We both have standing dinner plans with a few groups of friends, so those evenings out are reserved in advance. In addition, we visit with family, work in the garden, and take walks whenever we can get away. My biggest problem is that whenever I join a local club/group, they always try to make me an officer or committee chair. I have learned this year the art of saying, “NO!”

Luckily, our downtime is our own with no others in the house. If either of us has to put in a 14- or 18-hour day or work on the weekend, the other totally understands the situation and takes over household activities. When both of us are working long hours on projects together, I sometimes do wish I had a nonworking wife, for cooking, cleaning, and laundry!

Yes, freelancing can be crazy and hectic at times, but it is the best career in the world for many of us, and we wouldn’t trade it for anything else.

—Elizabeth Smith

A - For successful freelances, nothing comes more with the territory than a crazy work schedule. I juggle a number of projects simultaneously for myself, and I manage even more projects that are being handled by the writers and editors on my team. Between the sheer volume of work and the logistics of spanning more than 15 time zones, I could work around the clock if I wanted. But I don’t.

Because I work from home I don’t hit too much traffic getting into the office in the morning—unless I run into a cat on the stairs. The first place I make time for myself is going to the gym at 7:00 AM. I used to go after work, but I found it impossible to get there on a consistent basis. There would always be a deadline or a teleconference keeping me at my desk. By going first thing in the morning, usually nothing gets in my way. Best of all, the gym really energizes me for the day ahead.

During the day, I remain focused on work, so much so that I rarely take time for lunch. I’m working on that. Unless I know who’s calling and what it’s about, I try not to answer the phone after about 5:00 PM, and I make every attempt to get out of the office between 5:30 PM and 6:00 PM. Of course, that doesn’t mean I stop working. At night, I often deal with logistical matters and other business management tasks that it’s difficult to make time for during the day. By 9:00 PM, I’m usually pretty crispy and ready to decompress.

I’m selfish with my weekends and prefer to spend time with family and friends, although there are times when work must be done. If I have to work on the weekend, I get up early and get as much done as I can before the day officially starts. Then I try to immerse myself in fun activities so I’m too busy to even think about work. I admit that taking care of projects around the house often suffers as a result, and I’m working on that, too.

Where I’m most selfish is with my vacations. They are too few, and too far between, and I am committed to completely disconnecting from work. I don’t check voice mail or e-mail for the entire time I’m away, and I don’t answer my cell phone unless it’s personal. While I was in Sacramento for the AMWA conference, despite the jam-packed schedule of activities, sessions, and visiting with friends, I was able to stay on top of e-mail and keep my inbox pretty clean. Then on Sunday after the conference, my wife and I drove to Napa for a vacation, and boy was it heavenly to not even think about work for an entire week! I highly recommend it.

—Brian Bass
Here are seven tips:

1. Book a vacation (with a nonrefundable deposit) 9 to 12 months in advance, and stick to it. If you’ve paid good money that won’t be refunded, you are not going to cancel the trip because of a project deadline. Do not bring your laptop or iPad and, when there, keep your iPhone turned off except when essential. When clients have deadlines, tell them well ahead of your departure date, “I will be out of town May 1-18 but I promise that my draft/revisions/etc. will be submitted before I leave; however, if the project is delayed at your end and does not come to me until April 30th, revisions will unfortunately have to wait until my return on May 19. So we must plan well so that this does not happen.” Never even hint that you would be willing to delay your vacation! [NOTE: Be sure to tell them your return date is a day later than it actually is so that you are not expected to jump on a deadline within hours of your return, especially if you’re returning from somewhere that you know will be associated with serious jet lag on return.]

2. At least once every 2 weeks, take a very long lunch break—again, you have to “make it happen.” Make a date to meet someone for a leisurely lunch or a visit to a museum, etc., so you’re committed. Use the time to relax in a great restaurant with a view, or go shopping. When I was at Syntex in Palo Alto, several sales reps told me they took a few hours every week to wander around Stanford Shopping Center for an hour or two—just to get away from the constant pressure of work. “When the going gets tough, the tough go shopping.”

3. Join Toastmasters and consider that time as “fun time”—a nice break from the deadlines of work, fun people, fun topics. (If you feel stressed doing public speaking, or if you simply cannot do anything without turning it into a pressured business thing, obviously this is not a good idea for you.)

4. If a swimming pool (especially an indoor pool) is available, go there two or three times a week for a midday break. Bring someone else along to ensure that you won’t back out. If you don’t have a pool, find a great destination—walk a mile or two from your office and back at least three times per week. For instance, when my office was in Menlo Park, I was 1.25 miles from Stanford Shopping Center and walked over there almost daily—sometimes for lunch at Neiman Marcus Café with a colleague or friend, sometimes just to give myself a good break and some exercise. I was 2 miles from the Rodin Gardens/Cantor Museum, which had no entrance fee, so I sometimes walked there instead. The advantage of working as a self-employed freelance, especially in a home office, is that you can work a little late if you wish to take off during the day.

5. If you really cannot leave your office (eg, let’s say it’s snowing heavily), then learn and practice Savasana (yoga posture meaning “corpse”). Do this every single day for 20 minutes, wearing an eye pillow. Not only does it help you relax deeply by slowing your breathing and temporarily reducing blood pressure, the cumulative effect (if performed daily over several months) will be the miraculous infusion into your brain of a high dose of common sense, thus helping to prevent you from choosing to work 7 days a week and thinking about work 24/7. Note: the latter effect will take months of daily practice to reveal this benefit.

6. If at all possible, try to find at least a few clients you sincerely like, who are not stressed out themselves, who have humility rather than arrogance, and whose corporate mission is something you truly support and are passionate about. When you love the task and/or the people, it does not seem so much like work and you’re less likely to burn out.

7. Learn to say no! Sometimes you have to turn down work if accepting it means assaulting your immune system with excessive stress to meet yet another deadline. In this economy, saying no is difficult; but if you can possibly afford to turn down a project, do it.

—Cathryn Evans

A—Making time for myself is always a struggle, but it’s vital, so I find ways to do what’s most important to me. Using my business efficiency in my personal life lets me carve out a little more time. For example, I organize my errands around a trip to the bank to deposit checks or a trip to the gym to work out (a key part of my “me” time). I also try to enjoy every minute away from my desk, including listening to audio books when running errands.

The one part of my everyday life I never skip is working out, which gives me the energy and focus to work long hours, as well as getting me away from my desk for a while. Usually, I work for a few hours and then go to a class at the gym or work out at home (we have an elliptical machine, exercise DVDs, etc, in our basement). I belong to a yoga studio and try to get there at least once a week. I don’t always make that, but when I do, I feel calm and ready for anything. My goal is to take a yoga class twice a week every week.

At least once a month, I take an entire day off on a Saturday or Sunday. And once in a while, I’ll take a weekday off to do something fun with friends or family (like a chocolate tour or a visit to the Franklin Institute). While I often work longer on other days to make up for the time off, having an entire day out of the office gives me a much-needed mental lift.

Guilt-free travel is another key part of “me” time. My husband and I take long trips to explore new places (most recently, three weeks in China and Hong Kong). I do check e-mail every few days in case there’s anything urgent I need to respond to, but other than that, I leave the office behind.

—Lori De Milto
There is no doubt the recession is affecting many freelance medical writers. A friend of mine, who writes consumer health and patient education articles, recently told me that her business has decreased 40% in the past 18 months. Like a lot of us, she chose the freelance/entrepreneurial route over steady, full-time employment in order to be her own boss and have more control over her time and the type of work she does. Now, she says, she’s lucky to get enough new work to cover her basic expenses and is beginning to wonder if being self-employed is worth it.

She spends her day combing the Internet, sending out her CV, reaching out to contacts, and making cold calls to strangers. Sound familiar? Last week during a well-deserved rant of frustration, she told me, “Until things turn around, I might as well use this time to learn statistics so I can finally tell the difference between a risk ratio and an odds ratio instead of faking it.” Using the economic slowdown to learn other marketable skills is a good idea, and a lot of writers are doing it.

For those of us who find returning to a brick-and-mortar educational institution a major inconvenience and expense, other options are available for professional development. In addition to courses offered by professional organizations (such as AMWA), online training programs, e-books, and blogs can be a source of enrichment. However, none of these forums furnishes necessary on-the-job training that might secure a foot in the door of an employer.

The tele-internship is an emerging alternative to traditional training that is gaining popularity among medical writers and others seeking professional development. While offering plenty of opportunity for the kind of supervision, guidance, and feedback a mentor extends, the additional benefits inherent in the intern-supervisor relationship can enhance your attractiveness in the job market. Here are some benefits to participating in tele-internships:

- Interning is typically free of charge. You don’t have to pay your placement supervisor money for mentoring you; in exchange for your work they give their guidance and feedback.
- Internships are structured with specific tasks and milestones. Tasks are clearly defined and assigned over a finite period of time.
- Placement supervisors automatically provide mentoring. Mentoring you benefits the placement organization because it ensures the products you develop meet client expectations and organizational needs.
- You don’t have to be an expert. As an intern, you are not expected to be an expert. This allows you to enjoy your learning curve.
- Your supervisor can testify to your performance as an “employee.” Because you develop products your placement typically hires others to write, your internship mimics an employee-employer relationship.

In fact, landing an internship can be the best thing you can do for your job prospects if you want to become a CME writer. In many ways, internships are auditions. CME providers have the opportunity to get to know you and assess your work, and this can lead the way to paid work. Last week, a successful recruiter contacted me. She asked if I would be willing to train medical writers who call her seeking full-time positions at companies that develop and produce CME. She told me these writers tend to be accomplished professionals, experienced in other fields of medical writing—but they have no experience writing CME. On the other hand, her clients (CME providers) would like to fill their entry-level positions, but they are adamant that to be considered, an applicant must have CME experience.
Seven Must-Dos for Tele-Internship Success

1. Choose your placement wisely. Decide what type of CME provider would like to hire you in the future (medical education company, medical association, hospital, academic institution) and approach several about the possibility of interning.

2. Choose your supervisor wisely. The best supervisor is someone placed highly enough in the organization to give you a meaningful and credible endorsement but with enough time to supervise. Your supervisor should be someone who is intimately familiar with the work you will do and has done that kind of work himself or herself.

3. Write an agreement that establishes a concrete plan of action and outlines a list of mutual expectations for you and your supervisor. Your agreement should include start date, end date, number of hours per week, project description, days and times for regular check-ins, delivery of a written mid-internship evaluation, and your supervisor’s commitment to write an endorsement for you.

4. Make sure the assignments you undertake will benefit you. CME writers are most often hired to write needs assessments, create content (written and in slide sets), and develop evaluations and surveys; these are the types of assignments that are great to add to your portfolio.

5. Communicate, communicate, communicate. Responding quickly to e-mails, texts, and phone calls from your supervisor demonstrates your responsiveness and eagerness to succeed.

6. Ask questions when they arise. Fundamental to the intern-supervisor relationship is the understanding that you are not an expert. It is important to ask for clarification and feedback when needed.

7. Set up specific times to check in with your supervisor. By scheduling a conference call with your supervisor at least twice a week, you ensure a regular, timely exchange of information and demonstrate your punctuality and reliability.

CME: Dead or Alive? A Decade's Perspective

By Jonathan Marx, MBA
Senior Vice President, InQuill Medical Communications, LLC, Soquel, CA

In the last decade, we have seen a sea change in the objectives, methods, and funding of physician education. On the basis of turbulence created in 2006, some pessimists declared the future of CME to be dead. Six years later, we are seeing the dust begin to settle on an industry now more clearly dedicated not only to physician education but also to the improvement of medical practice and community health. What’s more, the US model, with regional customization, is being reviewed and adapted quickly in Europe and is spreading to other parts of the world as a basis for change. This means great career opportunities for those medical writers familiar with CME and able to execute on the new standards.

The turbulence referred to was created by the Accreditation Council for Continuing Medical Education (ACCME) when it released its updated Accreditation Criteria in 2006. Previous to 2006, the impact and effectiveness of physician education was measured by how many physicians attended an event (Level 1) and how satisfied they were with the location, accommodations, and content (Level 2). At that time, little attention was paid to what the physicians learned (Level 3), what new competence they had acquired (Level 4), how their practice behavior changed (Level 5), or how the CME might have a positive effect on health outcomes for patients (Level 6) and the community (Level 7).

What are these Levels you ask? They are the levels of potential and beneficial outcomes for a CME activity that were presented by Moore et al. in 2009. These levels were widely adopted by the CME community as the de facto Levels of Outcomes for physician education. The ACCME’s new criteria focused CME on a learner-centered, continu-
ous improvement model requiring CME providers to identify practice and knowledge gaps, create relevant learning objectives, and measure the outcomes of activities.

In its 2006 Accreditation Criteria, the ACCME also put tighter restrictions on commercial funding of CME activities. Pharmaceutical and device funders’ presence is now restricted to the exhibit hall, not the classroom. Funders can no longer have influence over content or speakers. CME now has to be fair, unbiased, and evidence-based. Simultaneously, the American Boards of Medical Specialties (ABMS) increased their CME credit hour requirements for specialists, creating the need for more CME activities.

The initial reaction of pharmaceutical and device companies was to pull back CME funding in favor of other marketing channel investments. According to the 2011 ACCME Annual Report, commercial support for CME dropped by 37%, from $1.2 billion to $752 million between 2006 and 2011. At the September 2012 CBI Forum on Educational Grants, numerous commercial support representatives said that CEOs are now keenly interested in the payback and benefits of investment in CME, just as they are in their marketing alternatives. CME now has to perform.

That brings us back to Moore’s Levels of Outcomes. Just as the ACCME has established new standards for a learner-centered continuous improvement model, and just as Donald Moore has established well-accepted Levels of Outcomes definitions, so too have commercial supporters now adopted requirements for measurement of Outcomes Levels in their new grant guidelines. They recognize the importance of improving patient health (Level 6) and community health (Level 7) as proof positive that their products are worthwhile and effective. To replace the former shoulder-rubbing between company representatives and physician clients, commercial supporters want to see that physicians are learning and applying CME principles in practice, to the betterment of patients and communities, and ultimately to the betterment of companies’ bottom lines.

New trends among commercial supporters include:
- Funding those grant proposals where educational objectives and measurements are aligned with outcomes;
- Creating requests for proposal processes where the grantor accepts only proposals responding to publicized company needs;
- Designating a select list of grantees who have been pre-approved for proposal submission.

The new world of outcomes measurement is here. The new world of a continuous improvement model for physician learning is here. CME providers are improving their skills in developing measurable outcomes from CME activities, and they are ploddingly moving up the Moore scale from Levels 1 and 2 (did physicians come, did they like it?), more reliably to Levels 3, 4, and 5 (did physicians learn, has their competence improved, are they changing the way they practice?). Innovative ways to measure improvements in patient health (Level 6) and community health (Level 7) are being discussed at conferences and piloted. Imagine physician education that has notable measureable impact upon four major US lifestyle epidemics: heart disease, diabetes, obesity, and allergy.

So, is CME dead or alive? Commercial support funding is down by 37% since 2006. According to the ACCME, in the same time period, support from registration fees, physician employer support and other noncommercial grant sources are up by 37%. If you look at total CME revenues between 2006 and 2011, the revenues are off by 1%.

However, if we take a panoramic view of the past decade (Table 1), we can see CME is doing fine. Commercial support is up by 32% since 2001, and income from registration fees, physician employer support, and other noncommercial grant sources has nearly doubled. Income from advertising and exhibits has nearly doubled. Total CME funding is up by 69%.

Change. Turbulence. It’s OK. We’ve evolved to a higher place. Take the long view—CME is doing great.

Author disclosure: The authors note that they are principals in InQuill Medical Communications, LLC, which creates continuing medical education content for a diverse clinical audience.

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References

Table 1. Decade of CME Revenues and Sources: 2001-2011

<table>
<thead>
<tr>
<th>Percentage of Revenues</th>
<th>2001</th>
<th>2006</th>
<th>2010</th>
<th>2011</th>
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<td>Commercial support</td>
<td>41%</td>
<td>50%</td>
<td>37%</td>
<td>32%</td>
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<tr>
<td>Other income*</td>
<td>48%</td>
<td>39%</td>
<td>51%</td>
<td>55%</td>
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<tr>
<td>Subtotal</td>
<td>89%</td>
<td>89%</td>
<td>88%</td>
<td>87%</td>
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<tr>
<td>Advertising/exhibits</td>
<td>11%</td>
<td>10%</td>
<td>12%</td>
<td>13%</td>
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<tr>
<td>Total CME revenues</td>
<td>100%</td>
<td>99%</td>
<td>100%</td>
<td>100%</td>
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</table>

Growth

<table>
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<th>Revenues ($ Millions)</th>
<th>2006-2011</th>
<th>2001-2011</th>
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<tbody>
<tr>
<td>Commercial support</td>
<td>−37%</td>
<td>32%</td>
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<tr>
<td>Other income*</td>
<td>37%</td>
<td>94%</td>
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<tr>
<td>Subtotal</td>
<td>−5%</td>
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<td>Advertising/exhibits</td>
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<td>93%</td>
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<tr>
<td>Total CME revenues</td>
<td>−1%</td>
<td>69%</td>
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*Registration, employer support, non-commercial support. Source: ACCME Annual Report data.
The Mentor-Mentee Cycle of Learning and Guiding in Medical Writing and Science

“Every piece of knowledge is something that has been shared by someone else. If you understand it as I do, mentoring becomes your true legacy. It’s why you get up every day—to teach and to be taught.”

— John Wooden, the legendary UCLA basketball coach; from Wooden J, Yaeger D. A Game Plan for Life: The Power of Mentoring

The term “mentor” has its origin in Greek mythology. In Homer’s Odyssey, Odysseus asked his loyal friend, Mentor, to nurture his son Telmachus. Thus, a mentor became known as a trusted guide and counselor, and this concept was carried many years forward, with a mentor seen as an older, experienced person taking a less experienced person under his or her wing. This informal relationship has evolved into formal mentoring relationships, where a mentor helps a mentee set clearly defined professional goals and the two work together to develop the skills the mentee needs to reach those goals.

The desire for a mentor is strong among medical writers new to the field, and AMWA is exploring ways to address this need among its members. Mentoring offers many benefits to both mentees and mentors, as well as to companies overall. Following are articles describing three different mentoring experiences—one at a large pharmaceutical company, and two at smaller, independent medical communication companies specializing in pharmaceutical writing.

The Medical Writing Mentoring Program at Amgen

Amgen, Inc, is one pharmaceutical company with a well-established mentoring program, which began in 2002. AMWA member Michele Vivirito played a key role in developing this program and continued mentoring writers there until her recent retirement. She guided dozens of writers during this period, including many newly hired writers who were making the transition from academia.

“Mentoring became one of the most rewarding aspects of my career at Amgen,” Vivirito says. “I’m very interested in helping medical writers develop leadership skills. I often ask mentees what is causing pain in their work lives and then strategize, together, behaviors that can reduce the pain.”

In 2011, Julie Wang, DPM, took over this leadership role. Now a senior manager in medical writing, she has more than 13 years of experience at Amgen and has gained expertise in a wide repertoire of skills related to clinical trials. This includes clinical research management, monitoring of clinical studies, and regulatory writing, and she has also been part of medical writing publications teams.

Amgen’s Global Medical Writing Department has 49 employees, 39 in the United States and 10 in Europe. Approximately three-fourths of these employees are medical writers, with the rest fulfilling essential roles in operations and administration. The mentoring program is primarily meant to help writers excel in their responsibilities at Amgen.
and build positive relationships within the fast-paced environment. The program follows these guidelines:

- Trust and confidentiality are key elements of the mentor-mentee relationship.
- Discussion content does not affect performance reviews or workload distribution.
- Mentors and mentees should not report to the same manager or be on the same product teams.
- The recommended structure of mentoring sessions is 12 weekly sessions, 30 minutes each.
- Session agendas should be shaped by the mentees.
- Mentor program leader facilitates kick-off meetings with mentor-mentee pairs to review expectations.
- Mentors meet with the mentees’ manager before initial session (to discuss mentee’s strengths and development areas) and after sixth session (to discuss mentee’s level of engagement in the program).

“We provide a guideline for the number and duration of mentor-mentee meetings, but the participants are free to modify the schedules according to their needs and workloads at any time,” Wang says.

“One of the key activities within a successful mentor program is assigning mentoring responsibilities to individuals,” Wang says. “One quality that comes to mind when I think about great mentors is the ability to empathize. Duration of experience and the ability to produce deliverables can certainly contribute to a mentor’s expertise, but to mentor effectively requires patience, tact, sincerity, and compassion. Mentors should be able to create a safe environment and communicate feedback in a nonjudgmental manner. Because of this tone of mutual respect, some mentor-mentee relationships informally last for many years.”

Wang adds that to gain the maximum benefit from a mentoring program, mentees should keep an open mind and be candid. “Don’t be afraid to make mistakes or admit to mistakes in front of your mentor. There should be an atmosphere of trust during your meetings, and mentors can help you see how challenges can become opportunities.”

Erica Rockybrand, PhD, a senior manager in medical writing at Amgen, says she has benefited greatly from having a mentor.

“It has allowed me to have a free forum to ask any questions and to share anything in an open environment. My mentor has always been there for me, both personally and professionally, and I truly feel that I have someone who really supports me. She has given great advice and always looks out for me. Her advice has helped me in my career development and I would not be where I am today without her.”

Yeshi Mikyas, PhD, ELS, CMPP, a global safety scientist at Amgen, says that having a mentor helped her develop her own style as a medical writer and helped her improve her “soft skills” of building relationships on a foundation of respect and establishing her credibility with other colleagues.

“Additionally, as a mentee I was also able to learn mentorship skills so I can be an effective mentor to others,” she adds.

Numerous successful people attribute their achievements to mentoring relationships. Yet many do not reach out to establish such a relationship. If you are new to medical writing, keep your eyes open for potential mentors who can help inspire you and help you navigate your career. If you are more experienced in your career, consider taking some newcomers to the field under your wings. Like Vivirito at Amgen, you may just find it to be the most rewarding experience of your career.

Author disclosure: The author notes that she has no commercial associations that may pose a conflict of interest in relation to this article.

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Medical Writing Fellowship for PharmD Professionals at Hamilton House

By Claire P. Santos, RN
Freelance health communicator and patient advocate,
Honolulu, HI

In today’s tumultuous global economy, it can seem that relatively few opportunities are available to support a career transition. Nonetheless, the occasional gem of an opportunity can be found.

Cindy Hamilton, PharmD, ELS, a past president of AMWA, has since 2001 offered a unique and challenging fellowship experience to colleagues who would like to improve their medical communication skills and explore careers in medical writing. This fellowship is designed for pharmacists, but the model can be adapted to accommodate people with other backgrounds.

Hamilton House and the Fellowship Development

Dr Hamilton once considered a career in teaching at a school of pharmacy but transitioned into the medical writing field, eventually founding and becoming the principal of Hamilton House Medical and Scientific Communications in 1990 in Virginia Beach, VA. Over time, with her desire to teach and to do more for her profession, she developed a program of short internships for senior pharmacy students. As she honed the design of that program, she ultimately developed a template for a fellowship experience that she
continues to perfect. She notes that experience gives a newcomer the competitive advantage that can help launch a new career—and that a fellowship can offer that experience.

**Hamilton House Fellowship Model**
The Hamilton House fellowship model provides a structured setting that centers on a 1-year contract (negotiable) and a commitment to AMWA’s standards for excellence and best practices in medical communications. Key features of the fellowship include:

- A contract that defines the fee schedule for medical communication projects and a weekly face-to-face meeting timeline for evaluation, feedback, and planning.
- An expectation that the fellow will develop his or her own goals and objectives for the year and that mutual goals and objectives will be set between the fellow and Hamilton House.
- The understanding that deliverables due by the fellow will include completion of a series of three progressively complex projects, including manuscript preparation, as well as opportunities to assist with Hamilton House’s projects.
- The understanding that Hamilton House (Dr Hamilton) will provide substantial oversight, to include rigorous editing and feedback.
- The requirement to become a member of AMWA, seek AMWA’s Essential Skills certificate, and participate in other educational and networking opportunities.
- Upon completion of the fellowship, a letter of recommendation for the fellow’s portfolio that will include a description of the educational and experiential components of the program.

**A Fellow’s Perspective**
Sericka McGee, PharmD, was working long hours as a community pharmacy manager when she decided it was time to develop a unique skill set in addition to her current professional skills. As many others have done, Dr McGee looked to the Internet for information about career options. A search brought her to the AMWA website, and Dr McGee realized that medical communications offered the potential to be creative and the chance to write for different readers in a variety of specialties. It held the added benefit that it could be pursued as either an adjunct or full-time career option.

Dr McGee enthusiastically started to fulfill coursework requirements for an AMWA certificate. As she became more involved with the organization, she learned of the Hamilton House fellowship. Recognizing that the fellowship could be an important career-building opportunity, Dr McGee applied for the position.

Today, after almost 2 years as the third fellow with Hamilton House, Dr McGee is an ardent supporter of the program. “The Hamilton House Fellowship has provided me with a very unique experience,” she says. “One advantage that this fellowship offers is the opportunity to work on a variety of topics without being committed to a specific drug or therapeutic area. I’ve worked on projects from chronic pain management to working with individuals in Australia on the prevalence of ghostwriting in medical literature.” Dr McGee also collaborated on a poster presentation at the 2012 AMWA conference.

Just as important, Dr McGee notes an improvement in her oral, written, medical evaluation, editing, data review, and literature-searching skills. Regarding the personalized learning plan that she developed with Dr Hamilton, Dr McGee says, “You get what you put in, so be proactive and take the initiative whenever you can.”

**The Takeaway**
Participating in a fellowship program such as the one designed by Dr Hamilton can be a comprehensive and beneficial means for a working professional to transition into the field of medical communication without engaging in a formal educational venture. Because the Hamilton House program allows for only one fellow at this time, and medical communication fellowships are otherwise few and far between, Dr Hamilton suggests that prospective medical writers and editors approach other medical communication professionals and entities with the idea of using the Hamilton House template to customize their own fellowship programs. To encourage mentor participation, Dr Hamilton also recommends making the proposal attractive, such as by volunteering to do the first project at no charge in return for feedback.

As her medical communication knowledge base expands and her career changes with it, Dr McGee offers this advice to the new medical communicator, “Make yourself stand out. Be proactive.” As she sees it, a person must take the initiative to get the fellowship, the experience, the business—whatever it takes to be successful. One of her favorite motivational quotes is “The toughest part of getting to the top of the ladder, is getting through the crowd at the bottom.”1

**Author disclosure:** The author notes that she has no commercial associations that may pose a conflict of interest in relation this article.

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**Reference**
1. The source of this quotation is often listed as unknown, although the Chicago Literary Hall of Fame website (www.chicagoliteraryhof.org/PersonDetails.aspx?PersonID=86) credits Chicago sportswriter and editor Arch Ward (1896-1955).
Medical Writing as a Drug Information Rotation for PharmD Students at Arbor Communications, Inc

By Dana L. Randall, MS, RD, PharmD, RPh
Director, Medical Writing and Scientific Services, Arbor Communications, Inc, Ann Arbor, MI

Like most medical writers, I fell into this career after falling into and out of a couple of other careers. I enrolled in the doctor of pharmacy (PharmD) program at the University of Michigan (UM) College of Pharmacy in 1995. The first 3 years of coursework were challenging and interesting, but I still didn’t really know what I wanted to be when I grew up. During the fourth year of all PharmD programs, students receive academic credit for a series of 5-week full-time rotations at various pharmacy practice sites. I took advantage of this opportunity by selecting a variety of rotations to explore the many career options available to a pharmacist. In March of my fourth year, 3 months before graduation, I completed a 5-week rotation at Medical Education Systems (MES), a medical communications agency in the Ann Arbor area. I loved it. It just felt right. I knew I had finally found my pharmacy niche. I could not believe people were getting paid to read and write about disease pathology and drug therapy.

My preceptor at MES, Joan K. Bradley, PharmD (currently President/CEO, JB Ashtin, Plymouth, MI), had completed her pharmacy degree at UM, and she preferred to hire pharmacists as medical writers because she knew we were trained to think like physicians. I started my career as a medical writer at MES in July 1999. After a year at MES, I worked as a freelance writer for about a year, and then I spent a year as a regulatory writer at Omnicare Clinical Research. For me, a medical communications agency was the most varied and interesting “practice site.” I went back to MES and eventually found my way to my current employer, Arbor Communications, Inc, a partner company of JK Associates, Inc.

The Arbor Communications office is in downtown Ann Arbor, MI, and we were approved as a practice site by the UM College of Pharmacy in 2008. The Arbor Communications rotation fulfills the requirement that every fourth-year PharmD student complete a drug information rotation. After the Pfizer Global Research & Development site in Ann Arbor closed in 2007, there were few local pharmaceutical industry opportunities for pharmacy students interested in exploring a nontraditional career. I volunteered to act as a preceptor for fourth-year PharmD students so I could offer current students the opportunity that Dr Bradley offered me.

We host four students per academic year, and to date, we have hosted 17 students. I say “we” because although I am officially the preceptor, the entire Arbor staff contributes to each student’s experience. Each student functions as an entry-level medical writer within our Medical Writing and Scientific Services staff. The first week on rotation includes a series of orientation meetings for students to interact with our staff of medical writers and also with members of our Editorial Support Services staff, including copyeditors, graphic designers, editorial project managers, and editorial assistants.

By the second week, the student is assigned actual client projects that may include development of promotional slide decks or drafting publications (eg, abstracts, posters, and manuscripts). During weeks 2 through 4, I also assign each student a journal club project that is presented to the 14 medical writers in our Medical Writing and Scientific Services Department, and a “lunch and learn” project that requires the student to research a topic, develop a slide deck, and deliver a 40-minute scientific presentation via web meeting to the entire company (JK Associates has 40 employees in two countries and six states). Students may also assist with research activities for business development opportunities and answer drug-information questions submitted by staff members. During the fifth and final rotation week, the student is expected to complete any remaining assignments and deliver the lunch and learn presentation on the last day.

Initially, I was hesitant to agree to become a preceptor because of the time commitment. Being a preceptor requires about 20 hours of my time per 5-week rotation (as well as time spent by colleagues in other departments). However, our time investment is offset by the fact that we have each student bill actual hours spent on client work. The PharmD students to date have been bright, capable, and fast learners, and have typically been efficient and productive team members. The students’ contributions to project work and business development activities benefit our bottom line.

I enjoy the challenge of tailoring each rotation to an individual student’s interests and career plans (some are headed to clinical pharmacy practice, some to retail pharmacy, and a few to the pharmaceutical industry or other nontraditional career choices). I especially enjoy being a preceptor when I have a student like Christina Gallagher (see sidebar) who is interested in a pharmaceutical industry career or other students who are interested in exploring alternatives to traditional pharmacy careers. Of 17 students, four have pursued medical affairs careers within the pharmaceutical industry. While my career choice may be considered nontraditional by some, it was certainly one of the best decisions I’ve ever made.

Author disclosure: The authors note that they have no commercial interests that may pose a conflict of interest with this article.

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Rotation #1: Medical Writing?

By Christina Gallagher, University of Michigan PharmD Candidate, 2013

During my first 3 years of pharmacy school, no one mentioned medical writing as a possible career path. When I learned that my first fourth-year rotation would be at Arbor Communications, I was apprehensive about what this mystery profession entailed. I pictured super-intelligent English majors hunched over desks overflowing with manuscripts in offices littered with medical textbooks, each writer requiring an intravenous caffeine infusion to keep up with the pressures of scientific publication. Thankfully, the medical writers I encountered were less manic in their approach to writing, and they very graciously shared their experiences with me during the 5 weeks that I spent trying my hand at medical writing.

Reflecting on my time at Arbor Communications, I am somewhat in awe of the diversity of projects that I was able to work on, and I’m reminded that the same traits valued in the world of pharmacy are similarly required for medical writers. Instead of a line of perfectly sharpened No. 2 pencils, the world of medical writing is better represented by a box of 64 Crayola crayons. From slide decks and poster presentations to abstracts and manuscripts, I learned that the field of medical writing is multifaceted and ever-changing. One of my projects was to research continuing education programs in the field of medical writing. I learned of professional organizations that offer certificate programs, webinars, workshops, and/or self-study modules for each part of the medical writing process. Just a quick look at the more than 100 workshops AMWA offers illustrates the wide breadth of skills used in medical writing.

Overall, my short stint as a medical writer was challenging and incredibly enjoyable. Interacting with professionals who were so well versed in heavy science yet who had the ability to articulate their knowledge created a dynamic and stimulating environment in the office. Understandably, traits such as organization, attention to detail, and the ability to work well under pressure are required for medical writers, but I had not expected to take as much satisfaction and enjoyment out of completing a given project as I did. Unlike my other rotations in a hospital or clinic setting, I felt like my voice as a medical writer was being heard by my health care peers. From an outsider’s point of view, I see that medical writers can play an integral role in educating our physicians, pharmacists, and nurses about new medications and the impact they may have on the lives of patients. The medical writers that I had the pleasure of working with certainly seemed up to this challenge and gave me a new appreciation for and interest in the world of medical writing and medical communications.

Online Resources to Help Establish or Maintain a Good Mentoring Relationship

3. Mentoring Basics (College of DuPage)
   www.cod.edu/teleconf/soaring/teleconference3/mentoringbasics.htm
4. Tips and Tools for Mentors (Mentor Michigan)
   www.michigan.gov/mentormichigan/0,4618,7-193-31889-100133--,00.html
5. Tips for Mentors (Peer Resources)
   www.mentors.ca/mentorideas.html
6. Mentoring Resources (National Mentoring Center, Education Northwest)
   http://educationnorthwest.org/nmc
7. “How to Start A Mentorship Relationship,” by Chrissy Scivicque
8. “Perspective: Top 10 Tips for Mentors,” by Philip S. Clifford and Joan M. Lakoski
   http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2010_10_08/caredit.a1000098
9. “Perspective: Top 10 Tips to Maximize Your Mentoring,” by Joan Lakoski
   http://community.sciencecareers.org/ctscinet/articles/2009/08/perspective-top-10-tips-to-maximize-your-mentoring.ph
10. Mentoring Tips (The Global Social Venture Competition, Women’s Technology Cluster, Social Fusion Program)
    www.gsyc.org/docs/MentoringTips.pdf
Calendar of Meetings

American Medical Writers Association
November 6-9, 2013
Columbus, OH

Health Academy, Public Relations Society of America
May 1-3, 2013
Indianapolis, IN
www.healthacademy.prsa.org

American Academy for the Advancement of Science
February 14-18, 2013
Boston, MA
www.aaas.org

Council of Science Editors
May 3-6, 2013
Montreal, Canada
www.councilscienceeditors.org

American Pharmacists Association
March 1-4, 2013
Los Angeles, CA
www.pharmacist.com

Society for Technical Communication
May 5-8, 2013
Atlanta, GA
www.stc.org

Association of Health Care Journalists
March 14-17, 2013
Boston, MA
www.healthjournalism.org

European Medical Writers Association
May 7-11, 2013
Manchester, UK
www.emwa.org

Drug Information Association Medical and Scientific Writing Communications Annual Forum
March 19-21, 2013
Phoenix, AZ
www.diahome.org

International Society for Medical Publication Professionals
April 29-May 1, 2013
Baltimore, MD
www.ismpp.org

For a complete list of meetings, visit Conferences > Related Meetings on the AMWA website (www.amwa.org).

NEW!
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You don't have to be in or around the medical profession very long before you hear the name of Sir William Osler. Some aspect of his life must have first come to your attention—his brilliance as a physician, his innovations as an educator—and oh, yes, his multitude of aphorisms and astute observations.

Some readers will merely know his name, while others will recall many things about him. To bring all up to date, let me recite—very briefly—some salient facts about him. A Canadian physician, he was born in 1849 and died in 1919. He graduated from McGill University Faculty of Medicine, where he later became professor of medicine, then moved to a similar post at the University of Pennsylvania. Subsequently, he became Johns Hopkins’ first professor of medicine, creating the first specialty residency training program and the first bedside clinical training for students. Arguably, he is still best known for his multiple, sagacious, practical aphorisms—most of them applicable today.

Little known is that he was prankster, with a great sense of humor. He wrote a number of humorous pieces under a pseudonym. And, not mentioned often, he was a great public speaker.

Although he had no known utterances specifically on writing, many of his sayings are applicable to some aspects of writing:

To study the phenomena of disease without books is to sail the uncharted sea, while to study books without patients is not to go to sea at all.

He was also an outstanding bibliophile and a founder of the Medical Library Association, which just celebrated its 100th anniversary. He willed his personal library of 8,000 volumes on the history of medicine—a massive number for any individual—to his alma mater, McGill University.

It is much simpler to buy books than to read them and easier to read them than to absorb them.

No doubt this wisdom came from close observation of medical students, and maybe even some physicians. Maybe even some people in other fields.

Observe, record, tabulate, communicate. Use your five senses. Learn to see, learn to hear, learn to feel, learn to smell, and know that by practice alone you can become expert.

What a command for physicians—in fact, all kinds of healers. Certainly it is applicable to writers, all writers, not just medical writers. How diminished the writing world would be if we writers—medical, sports, political and everything else—didn’t carry out these imperatives, almost daily.

There is no more difficult art to acquire than the art of observation, and for some men it is quite as difficult to record an observation in brief and plain language.

Any writer who has had contact with a number of physicians can swear allegiance to this aphorism. If untrue, there would be far less need for medical writers, so maybe we should thank Osler for making this so clear.

Most of Osler’s other pithy observations pertain more directly to the practice of medicine. But I cannot let this opportunity pass without reminding readers (or letting less-exposed readers know) of the impact of some of his outstanding and oft-repeated maxims.

One of the first duties of the physician is to educate the masses not to take medicine.

Even though today we have so many thousands more effective medications, his wisdom still prevails, as many authorities agree that, even today, too much medication is prescribed.

The good physician treats the disease; the great physician treats the patient who has the disease.

In the early days of medicine, maybe physicians were more apt to follow this dictum—possibly because they had too few specific treatments to use and they had to rely on bolstering the patient’s inner curative systems. Today, we often forget the patient while treating his disease. So, even a century or so ago, Osler had insight way ahead of his time.

And to this physician-writer, Osler’s greatest dictum of all—pertinent in Osler’s day and every bit as pertinent today—was this one:

Listen, the patient is telling you the diagnosis.

Wise man, outstanding physician, creator of many of today’s standards such as clinical exposure and residency training, writer extraordinaire, highly regarded bibliophile and author, father of more than 10 eponyms, with a dozen buildings named for him around the world—and that’s but a miniature reflection of who the man was. He truly deserved the title of “father of modern medicine.”

And we in AMWA can proudly call him “fellow writer.”

With one exception, the quotations in this article are available at: lifeinthefastlane.com/resources/oslerisms. “Listen, the patient is telling you the diagnosis” is available at en.wikipedia.org/wiki/William_Osler and many other sources on the web.
LinkedIn Recommendations: How To Make Them Work For You

Cyndy L. Kryder, MS, CCC-Sp

Medical Communications Consultant, Phoenixville, PA

The popularity of LinkedIn, the job-hunting and professional networking platform, continues to grow. The digital analytics company comScore reports that in the second quarter of 2012, the number of unique LinkedIn visitors (including members and nonmembers) averaged 106 million, an increase of 30% over the previous year. As of August 2, 2012, LinkedIn had more than 175 million members.

By now, many professionals, including AMWA members, have created a LinkedIn profile and are using the site for networking, prospecting, and job hunting. According to the results of the 2010 AMWA Member Survey, 80% of respondents reported using LinkedIn. The question is, are you using LinkedIn to its fullest capacity?

Getting the most from LinkedIn involves more than just creating a profile and sitting back and waiting for people to find you. To network effectively with this social media platform you need to join groups and actively participate in the discussions taking place within them. The insight and resources you share in your flawlessly worded responses will drive people to your LinkedIn profile, where you have highlighted your expertise and competencies, and shared recommendations from previous clients, colleagues, and mentors. Have you been asking them to recommend your work on LinkedIn, haven’t you?

If not, then you’re missing out on a valuable feature of LinkedIn. Take a look at the recommendations on some of your connections’ profiles. As you read them, you quickly glean details about the work they do, the clients with whom they work, and the skills they have. If you were a prospective client, recruiter, or employer, this information would be important to you. Such first-hand recommendations generally hold more sway than do mere words on a resume. Unfortunately, some people are reluctant to approach their clients and colleagues for recommendations. When you work well with a colleague on a paid or volunteer basis and want to highlight the work you accomplished, it is perfectly acceptable to ask him or her to recommend you on LinkedIn. Likewise, if you have successfully concluded a freelance project and your client was happy with the deliverable, then take advantage of the goodwill that exists by requesting a brief recommendation. Here are some tips on how to do so:

• Consider carefully who might be able to provide you with a recommendation. Which of the clients with whom you worked directly was satisfied with your work and might be willing to take the time to comment on your skills? If you’re approaching a mentor or colleague, then be specific about what you would like discussed in the recommendation.

• Because only people with LinkedIn profiles can provide recommendations through this platform, do a quick search to determine that your contact is indeed active on LinkedIn. Additionally, your contact needs to be one of your LinkedIn connections. If you haven’t already connected, then now is the time to do so.

• Approach the person after the project is finished, while the experience is still fresh. Don’t wait months to ask for a recommendation. By then your contact has moved on to other projects.

• Use the LinkedIn recommendation tab rather than standard e-mail to ask for the recommendation. (This brands the request with the LinkedIn identity, making it stand out from regular e-mails.) Click on the profile tab, then on recommendations in the drop-down menu. Click on the request recommendations tab and choose the person.

• Personalize the message request. Even though LinkedIn provides canned text in the message section, it is to your advantage to craft a specific note that includes details about the project for which you’d like a recommendation.

• Avoid sending out blanket requests to multiple connections using a generic message. This seems too impersonal.

• Do follow up with a short thank-you message via LinkedIn once you have received the recommendation.

• Don’t be disappointed if people don’t recommend you immediately. Writing a LinkedIn recommendation does not take a lot of time, but it does still take some time. A busy project manager or department director just might not have a minute to spare. Don’t take a lack of response as a negative comment on your abilities. You might want to send a second request if you haven’t received a response in a month; however, don’t turn into a pest. Respect that some people just don’t feel comfortable writing an electronic recommendation and they may be reluctant to admit that to you.

• Always include the URL to your LinkedIn profile in your resume and in your email signature. Make it easy for
people to discover the wonderful things people are saying about you!

To make it even easier for people to recommend you, LinkedIn recently introduced its new endorsement feature. People who are acquainted with your work can go to your profile and with one click of the mouse endorse a specific skill you identified in the skills and expertise section of your LinkedIn profile. Granted, a simple endorsement like this doesn't offer any details about the project, as would a full recommendation; however, for time-pressed colleagues and clients, it may be your best option.

References

Mentoring Connections on LinkedIn
In this mentoring-themed issue of the AMWA Journal, what better place to ask for the wise advice of our fellow AMWA members than on the discussion board of LinkedIn? I started a discussion asking members to share their mentoring experiences and received 13 replies.

Stephanie Roberson Barnard, who found her mentor 16 years ago, noted several aspects of the mentoring relationship that created a positive atmosphere for her and her mentor: mutual respect for each other's ideas and time, a similar work ethic, a shared love of communication skills, and common interests in their personal lives.

Katherine Daniel was mentored by the president of her local AMWA chapter when she started her medical writing career years ago. She recounts her experience: “She took me under her wing and sent freelance work my way, starting me off with safety narratives, then ‘graduating’ me to CSR shells. Thanks to her guidance and my AMWA core certificate, I was eventually able to secure a full-time position in regulatory medical writing.” As a result of her positive experience, she tries to “pay it forward every chance I get.”

Blog Log
By Debra Gordon, MS
President, GordonSquared, Inc
Williamsburg, VA

Blogging About Mentoring
Whether you formally (charging for your time) or informally (out of the goodness of your heart) mentor others, or whether you’re a mentee, it’s important to understand the relationship and keep your mentoring skills sharp. These blogs may help:

Mentoring Matters Blog
www.centerformentoringexcellence.com/blog
This blog comes from the Center for Mentoring Excellence (yes, there is such a thing). The tag line is “Motivate, Inspire, and Grow Through Mentoring,” and the topics target both mentors and mentees. Recent topics include:
- Getting to Know You: Conversation Starters for Mentors and Mentees
- Tips for Focusing Mentoring Conversations
- 10 Tips for Managing Mentoring Meeting Time

Mentoring Works
mentoring-works.blogspot.com
This blog is written by Australian Ann Rolfe, who describes herself as the country’s “leading specialist in mentoring.” In a blog post entitled, “Do Managers Mentor?” she reported the results from a poll she ran on the site: 53% of respondents said they were mentored by a manager in the past; 33% had managers currently mentoring them; and 13% had never been mentored by a manager (participants were allowed multiple responses). Other recent topics include the motivating impact of the Paralympics; whether managers should mentor their staff; and “Mentoring Strategy—Ten Keys to Excellence.”

Management Mentors
www.management-mentors.com/about/corporate-mentoring-matters-blog
This site will disabuse you of the notion that mentoring is a one-on-one relationship that can be done by anyone willing to put the time into it. The blog is written by Management Mentors, which brings formal mentoring programs into corporations with, among other things, e-mentoring software! Recent posts include:
- How to Get Your University to Support an Alumni Mentoring Program
- How Alumni Mentoring Programs Can Help You Recruit Talent
- The Best Mentoring Takes Time

I hope many of you took the time during the national meeting in Sacramento to do some mentoring, even if it was just over a glass of wine in the bar, or opened yourself up to mentoring. There is no better way to learn!
Genevieve Long is grateful to her mentor, Lori De Milto of the Delaware Valley chapter, for advice and encouragement that led to her participation on a panel about freelancing, establishing a business, and even becoming a chapter president.

Being a mentor doesn’t need to be an official position. Everyone appreciates a good tip. Suzanne Canada notes, “I was always talking to other members at the events about how they got started. I think that sharing your opinions about how to be the best medical writer you can be is valuable, as well as pointing new or interested parties in the ‘right’ direction.”

At the AMWA annual conference each year, first-time attendees are encouraged to attend the Conference Coach Connection, held just as the conference is about to get under way. Conference coaches give new members more confidence in navigating the annual conference. Marjorie Winters explains, “Keep in mind that the mentoring is designed for the annual conference only. If it goes beyond that, it’s a bonus, but the commitment by the mentors is to help a ‘newbie’ get through the conference.”

Anita Misra-Press wrote of her first conference: “The conference coach connection is wonderful for breaking the ice and meeting people. I was very touched by the openness and willingness of almost every single person at the conference to help newcomers like us feel welcome and provide guidance.”

LinkedIn offers many mentoring groups across an array of professions. Some examples are: Professional and Amateur Mentoring Group, Women’s Leadership and Mentoring Alliance (WLMA), and the International Mentoring Association. The Medical Publishers and Editors Group, with 33 members, is a networking group and platform for exchanging ideas on challenges of this field. This group is focused on, “The need to exchange ideas and innovations globally, staying on top of the latest guidelines and regulations on matters such as copyright and plagiarism, and unique methods to keep abreast of medical science.” The group is not specifically mentor-focused, but through the networking and information provided may contribute valuable career guidance.

The networking aspects of LinkedIn make it a wonderful forum for finding a mentor or becoming one. AMWA members work in many different types of medical writing all across the nation. On our LinkedIn group, feel free to ask a question or answer one. You can help someone get started, steer them in the right direction, or just make a new friend.

Until next time, looking forward to connecting with you on LinkedIn!

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For more information on the program, visit www.pharmacy.umaryland.edu/regulatoryscience

For more information on the Maryland/FDA collaboration, visit www.cersi.umd.edu
If you have ever received an e-mail notification that you’ve won the UK Lottery, you know that all you have to do is reply with your bank account number, date of birth, and Social Security number to have a staggering amount of money deposited into said account. Easy money, right?

These days, most of us are familiar enough with these so-called “phishing” scams not to fall for such awkward, rudimentary attempts to steal our personal information. But not all computer security risks are so obvious. The more sophisticated and dangerous ones are often so subtle you won’t realize you have a problem until it is too late.

Malware, malicious software designed to do digital harm to you and your computer, includes spyware, key-stroke loggers, Trojans, worms, and viruses. Though there are technical differences among these groups, we less techy people tend to lump them all under the category of computer viruses. There are also phishing e-mails, such as the above-mentioned UK Lottery, whose sole purpose is to trick you into revealing personal or financial information that you do not want falling into the wrong hands. With such a wide variety of threats, and with our growing dependency on computers in everyday life, staying safe online may seem like a daunting task. It doesn’t have to be, given the right software and a good deal of vigilance. What follows are some basic dos and don’ts to make you a safer netizen.

**An Ounce of Prevention**

Is it essential to have an antivirus program running on your computer at all times? For Windows-based personal computers (PCs) the answer is a resounding “Yes.” Even Apple computers are encountering increasing pressure from Mac-targeted botnets and other malware, and can harbor and spread PC and Mac viruses over shared networks. You should set your antivirus software so it regularly and automatically updates its signatures—the software’s library of instructions that identify and mark malware for removal. Because new malware is released daily, constant vigilance on the part of your antivirus program reduces your risk that something new will sneak by. These days, most antivirus programs are set by default to update automatically on a regular basis. Normally, your program will alert you if the default is NOT set to automatic updates. Every antivirus program should have a Tasks or Updates option you can customize and set.

A good antivirus program will also automatically scan your e-mails and any websites you attempt to visit, in addition to your hard drive. Recent, comprehensive reviews of virus software for PC (bit.ly/aAyXOw) and Mac (bit.ly/Lx3DDb) are available at *PC Magazine*. Norton (available for PC and Mac, at [Symantec.com](http://www.symantec.com)) is one of the most wide-ranging programs available. It comes in various options, the most comprehensive of which costs $89.99 and will protect up to three PCs under the same license. It also provides firewall protection, another essential tool. Hackers will often scan networks for unprotected computers to control. A firewall can prevent a hacker from accessing your computer.

Another feature a good virus protection affords is encryption of personal information on your computer so that, in case hackers do gain access, they will not be able to steal your identity and access your finances. Norton and MacAfee ([macafee.com](http://www.macafee.com)) can also store personal details and credit card information in an encrypted form, and automatically fill in fields for online purchases. That way, you are protected in case a key-stroke logger has infected your computer and is recording everything you type—logins, passwords, account numbers—for the benefit of a hacker.

**Suspicious Minds**

Elvis may not have approved of the habit, but being suspicious online is a good thing, even when it comes to friends. The problem with malware is that it often spreads by exploiting a user’s network of colleagues by using e-mail contacts, for example. So if your friend sends you an e-mail that says, “You’ve got to watch this video,” think before you click on the link. Maybe even call, text, or e-mail to ask if your friend actually meant to send it. If not, break the bad news that he or she has been hit by a virus.

With respect to phishing, be aware that no self-respecting online service provider—especially a bank or credit card company—will ever ask you for your account password by e-mail. Any e-mail requiring you to disclose your password to avoid “interruption in service” or “suspension of your account” should set off loud alarm bells. Never click on a
link from such a message and never respond to it. If you want to verify your account status, log into your account from a new browser window, or pick up the phone and call the company.

Online safety can be a chore, but the consequences for shirking can be heartbreaking and costly. Programs that protect against malware can reduce your work, but don’t be lulled into thinking you are completely safe. Make sure to run full system scans with your protection software on a regular basis (schedule it to run at night, as it can take several hours). Don’t share passwords. Don’t open unknown attachments or click on unfamiliar, unexpected links. Maintain a healthy level of vigilance and stay safe.

References

By Jeanne McAdara-Berkowitz, PhD
Principal, Biolexica LLC, Longmont, CO

TECH TIPS

Is Somebody Watching You?

A mixed blessing of being a knowledge worker is that you can probably work from just about anywhere—coffeeshouse, park, airport, or airplane. But if you use your computer outside the privacy of an office, have you considered who might be peering over your shoulder, either casually or intentionally? Plenty of pharmaceutical companies and academic centers are clustered geographically, and their employees probably use the same airports and other public spaces that you do. In other words, there could be many people around you who really do care about that document you have open on your screen.

One way to shield proprietary information from prying eyes is to use a laptop privacy filter. These adhesive films feature an internal optical structure that darkens the view for anyone not positioned directly in front of the screen. While some manufacturers claim that gold-toned filters improve visual clarity, the difference seems minimal. Some models are reported to increase screen glare, so read user reviews before buying.

Laptop Privacy Screens
Buy at: Manufacturer websites; office supply stores; online retailers such as Amazon.com
Brands to consider: 3M, Targus, Fellowes
Cost: $30–$50

Rescue Wasted Time in Your Day

If you ever feel like your productivity doesn’t match the hours you put in during the workday, you may want to consider activity tracking software. RescueTime records how much time you spend actively engaged with the various applications you have open and, once a week, sends you a report that breaks down how much time you are spending on these activities. Easy setup lets you customize activities on a 5-point scale from your most productive (I chose Microsoft Word and Excel) to your most distracting (for me, Facebook and news sites). According to the developer, RescueTime allows you to “spot inefficiencies in your day, become better at self-managing, and make measurable changes that impact your time in a positive way.”

The Pro version offers additional features, such as the ability to block distracting websites for a set amount of time, track offline time, and set goals. Team versions are available that give managers access to analytics for multiple users.

RescueTime (www.rescuetime.com)
Cost: Basic app is free for individuals; special features and team pricing start at $9 per month or $72 for annual contract.
STRATEGY ReDefined

RPS, the Next Generation CRO, provides comprehensive global Phase I-IV clinical development solutions to the Pharmaceutical, Biotechnology, Medical Device and Diagnostic industries. By combining our highly experienced clinical research operations infrastructure with the industry's largest resourcing engines, RPS is uniquely positioned to offer our Customers a broad spectrum of outsourcing solutions. These solutions range from globally Embedded functional and cross-functional programs to enhanced global full-service solutions, and are powered by highly experienced project teams providing innovative, seamless, cost-effective and high quality services. With more than 3,000 employees, RPS operates in 46 countries across the globe.
INAGURAL PRESIDENTIAL ADDRESS*

By Douglas Haneline, PhD, 2012-2013 AMWA President

I am making my first speech as President of the American Medical Writers Association, and I cannot tell you how much your confidence in me moves me. Twenty-six years ago I joined AMWA in the hopes of finding out the conventions of medical writing so I could teach them to pharmacists and nurses, and, well . . . I stayed. I attended my first annual conference in Chicago in 1987 and haven’t missed one since. I’ve been a presenter, a workshop leader, a chapter president and delegate, the Annual Conference Administrator, a member of the Executive Committee (EC), an elected officer—and in every one of those roles I have been enabled to succeed by the goodwill and intelligence of the members of our wonderful association, including many of the people in this room, and many others, over many years. I am looking forward to a year of leading AMWA’s effort and accomplishment as President, and I know that if I need your help or advice, you’ll happily provide it.

This past summer I talked individually with all the members of the 2012-2013 EC about their feelings toward AMWA, issues they thought were important, and plans they had in their respective roles and departments. I specifically asked them about a theme for 2012-2013 that I have and was pleased when they liked it: “AMWA: Building on Our Roots and Growing into Our Potential.” This theme expresses my core feeling about AMWA at this point in its history: we are well positioned for success, but we need to make changes so that when opportunity knocks on our door, we are ready to open it.

During the spring and summer, the EC has been developing plans for initiatives for the coming year. These plans involve five related areas: infrastructure improvements, enhancement of member resources and membership, increasing educational products and offerings, improving internal and external communications, and defining the profession/developing a certification program. Details of these plans have been discussed with the AMWA Board of Directors and will be shared with the membership at large.

These plans and initiatives detail what we need to start or accomplish during this coming year because AMWA is at a critical turning point in its history. In our first 72 years, we gave a name to a developing profession, changed from being primarily physician-editors to being professional writers, developed and revised a code of ethics, developed and improved an educational program, hired the first of three executive directors, and grew from a few hundred to over 5,000 members.

How did we do all this, with a relatively small membership base and no large-scale or continued support from any one source, or an endowment that yields more than a few thousand dollars a year? Our mojo comes from our loyal and dedicated members who willingly devote huge amounts of time to AMWA projects. We know this because so many of those people, even if they are no longer part of AMWA, were active in the memory of current members, or they are active right now. These people don’t ask for plaques or certificates, though it is important that we recognize them—as we do! They did and do these things because they see AMWA as a place where they can make a difference in the professional lives of medical writers. Eighteenth-century philosopher Edmund Burke describes society as a compact between the dead, the living, and the yet unborn. Less grandly, perhaps, that describes AMWA: we active members benefit from the work of those in the past, and we work to benefit AMWA members in the future. We also know that AMWA possesses a special quality because of what new members say: how warm and welcoming AMWA is, and how easy it is to get involved.

So, we have good cards in our hand: a solid education program, a highly qualified membership, a strong sense of professional identity, an excellent esprit de corps, all backed by sound financial management and a well-qualified headquarters staff. We need all those things because we have a lot to do.

The profession is changing rapidly. Where medical writers work and under what conditions are changing rapidly. The continuing professional needs of medical writers are expanding and changing. Medical writing is done globally, and writers everywhere are looking for information about their craft. We need to remain the place where people come to find all that out. The 2012-2013 initiatives address these and other challenges. But we have one more challenge: to sustain our every-member-counts ethos, but, at the same time, become more efficient and more effective. In other words, we need to manage our downtown specialty shop more efficiently, but we don’t want to turn it into a big box store. Speaking for the EC, the Board, and the staff, I invite you to become a part of our efforts to meet these challenges.

*Delivered at the AMWA Annual Business Meeting, Saturday, October 6, 2012, Sacramento, CA.
**AMWA's Medical Writing Certification Initiative: Where Are We Now?**

By Thomas P. Gegeny, MS, ELS, CMPP, and Karen Potvin Klein, MA, ELS, GPC

2011-2012 Chair and Chair-Elect, AMWA Certification Commission

**Historical Background**

AMWA’s current medical writing certification initiative has its roots in a 1996 AMWA task force that recommended further research into certifying medical communication professionals. Focus was placed again on certification as part of the work undertaken in 2007-2008 by a Long-Range Planning Committee appointed by AMWA leadership. In a strategic analysis of AMWA and its environment, the Committee determined that an organizational weakness was a “lack of certification in a competitive market.” In 2009, an AMWA task force was formed and reached out to allied organizations (the Accreditation Council for Continuing Medical Education [ACCME], the Board of Editors in the Life Sciences [BELS], the Council of Science Editors [CSE], and the International Society of Medical Publication Planners [ISMPP], among others) to gather their perspectives on the medical writing profession. After researching other certification programs related to medical writing, the task force recommended, as suggested by the Long-Range Planning Committee, that AMWA pursue developing a medical writing certification program.

In a 2010 survey, AMWA members were asked, “Is professional certification with a competency examination desirable for the medical communication profession?” Of the 1,339 respondents, 65.6% indicated “Yes.” Thus, based on all of these recommendations, the AMWA Board of Directors established the Medical Writers Certification Commission in 2011.

**What Certification Is—and Isn’t**

Certification involves an assessment process and usually requires that the applicant have relevant work experience. A credential is granted by an independent, standard-setting body, and it is earned through demonstration of knowledge and/or competency through an examination. This is the model AMWA is working toward developing.

By contrast, a certificate typically is given after an educational process, may be open to applicants regardless of their level of experience, is granted by an association or institution, and indicates completion of course work. This is AMWA’s current educational model, which is supported by the many workshops offered at the annual conference and chapter conferences and by the self-study modules. This program is central to AMWA’s mission and will continue to be a vibrant, valuable, and essential part of AMWA. In the future, individuals can pursue certification, earn certificates through workshops or self-study modules, or otherwise participate in AMWA’s educational activities.

**Medical Writing Certification Commission: Charge and Structure**

The Medical Writing Certification Commission was established to initiate, evaluate, maintain, and oversee a certification program for medical writers. The Commission was charged with overseeing matters related to certification of medical writers; creating application, examination, recertification, and appeals processes; and recommending certification policies and ongoing improvements to the certification process. Certification will be open to medical writers worldwide and is not limited to AMWA members.

The Commission currently has six members (Figure 1). The number of at-large members may change over time. The plan is for at-large members to serve staggered 2-year terms, which will allow for some consistency while regularly infusing the Commission with fresh perspectives.

**Commission’s Interface with AMWA’s Structure**

Eventually, the Certification Commission will become independent; until then, AMWA will maintain fiscal oversight of the Commission, which will have separate allocated funds within AMWA’s budget. The Commission meshes with AMWA’s organizational structure to encompass both AMWA volunteer leaders and AMWA staff (Figure 2). AMWA will provide staff support and facilitate business matters (eg, provide fiscal oversight and access to legal advice). To facilitate communication with AMWA’s leaders, the Commission Chair is currently a member of AMWA’s Executive Committee and Board of Directors.

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*Adapted from an Open Session presented at the 72nd Annual AMWA Conference, Sacramento, CA, October 6, 2012. For a comprehensive set of FAQs about this topic, please go to www.amwa.org/default/publications/AMWACertificationBackgrounder.pdf*
Progress to Date

Examination Vendor Selection. To determine the best vendor to help in examination development, AMWA’s Executive Director, Susan Krug, CAE, initiated a competitive request for proposals. Schroeder Management Technologies (SMT), based in Clearwater, FL, was chosen. SMT has an excellent reputation in the examination development industry, and its personnel include psychometricians and other experts in writing examination questions. Some of the ways SMT helps professional organizations to create certification tests include job analysis surveys, question writing, examination assembly and administration, and scoring.

Definition of Competencies. From fall 2011 to winter 2012, Commission members assembled a set of profession-related materials and resources, including material from AMWA’s workshops and the competency model developed by the Drug Information Association (DIA) Medical Writing Special Interest Area Community1 to help develop an outline of the knowledge, skills, and abilities (KSAs) of minimally competent medical writers. After drafts were exchanged among Certification Commission members, a Job Analysis Panel was formed (see Acknowledgment) and the panel met with SMT in March 2012 for 2 days to create a final KSA outline. This panel deliberated about the key components (domains) of a medical writer’s competencies. The panel began with AMWA’s own definition of a medical communicator.

Medical communicators write, edit, or develop materials about medicine and health. They do this by gathering, organizing, interpreting, and presenting information in a manner appropriate for the target audience. (www.amwa.org/default.asp?id=420)

The panel decided that in addition to the tasks mentioned above, medical communicators must also evaluate materials in many ways, so “evaluating” was added as a domain. Of note, the panel believed that ethics should be part of all five domains when considering tasks done by medical writers (Figure 3).

The Job Analysis Panel considered several key questions when designing the KSA outline (see box below). Incorporating these key questions throughout the process will help to ensure that the appropriate test design concepts are accounted for (crucial in eventual test design), and that the content for the examination is relevant and applicable.

### Key Questions Behind Each Knowledge, Skills, and Abilities Component
- Is the component important to assess competency across all medical writing settings?
- Is it clearly written?
- Is it assigned to the appropriate domain within the outline?
- Is it performed by “practitioners” regularly?
- Are there errors or omissions?
- Is it testable?

The Job Analysis Survey

The next step was creation of a job analysis survey, a standard tool used in creating a certification examination because it can help establish a uniform set of professional criteria or expectations against which test content can be developed. This survey is designed to evaluate the appropriateness of the KSAs identified by asking respondents the degree to which the set of KSAs are important in their jobs. The results of the job analysis survey establish a foundation for the examination program by giving the examination developers direction regarding content. The survey results also provide an all-important link between assessment and practice and provide legal defensibility for the test content.

To learn whether the concepts developed by the panel reflected the experience of medical writers at large (includ-
ing, but not limited to, AMWA members), the Job Analysis Panel worked closely with SMT during spring 2012 to create an online survey for the medical writing community. In addition to feedback on the KSAs, the survey requested demographic and professional information about respondents.

In April 2012, AMWA alerted its members (and members of BELS, DIA, ISMPP, and the Society for Technical Communication—more than 10,000 people overall) that the survey would be available in a few weeks and explained the importance of participation. The survey was beta-tested by the panel and Commission members, went live on April 28, and remained open until July 8. A total of 1,177 individuals completed the survey, a return rate of 8%, which SMT indicated is average for an unsolicited survey.

Review of Survey Responses
Among the demographic data collected in the survey were age, number of years of experience, geographic location, highest educational degree, and professional designations (Table 1). Nearly 80% of respondents were women, mirroring AMWA’s membership (84.4% of whom are female). Respondents were from every continent and world region; nearly 80% were from the United States, and 12% were from Europe. The respondents’ three most common fields of university study were life sciences (41.7%), health care professions (13.5%), and English or other humanities (12.5%). Nearly three-quarters of respondents (72%) had more than 5 years of experience in medical communication.

Respondents came from a broad range of work settings (Figure 4). Within those settings, 36% of respondents said they were primarily writers, 12% were primarily editors, and 33% were both writers and editors.

Mean Scoring of Item Importance
Respondents were asked to rate each of the 68 KSAs within the survey from 1 to 5. A score of 1 indicated “of no importance,” 2 indicated “of little importance,” 3 indicated “moderately important,” 4 indicated “very important,” and 5 indicated “extremely important.” For all KSAs, even the lowest-ranking items scored in the “moderately important” to “very important” range (the lowest mean score was 3.60). Overall, 53 of 68 line items were ranked at least “very important” (4.00 or higher). These results indicate that most respondents believed these KSAs were important to the competent practice of medical writing. Importantly, more than 93% of respondents noted that the job analysis survey either “completely” or “adequately” described the critical tasks required for competent medical writers. A list of all the KSAs and their scores can be found in the Appendix online.

Validity of the Survey
Statistical analysis of the results was done by the SMT staff. Cronbach’s coefficient alpha reliability estimate was calculated to evaluate the internal consistency of the instrument. This statistic is bound between 0 and 1, with values closer to 1 showing higher instrument validity (that is, that the tasks worked well together to measure the KSAs requisite in medical writing). Cronbach’s coefficient was calculated by using the SPSS statistical program (Statistical Package for the Social Sciences, version 17.0, IBM). For this survey, the coefficient alpha reliability estimate was 0.97 for the importance statements. This value indicates that the survey has high consistency within the items measured.

In addition, subgroup analyses were performed according to years of experience, geographic location, and work setting. Although there were some statistically significant differences in responses among subgroups, the lowest average rating (3.59) was still within the “moderately

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Percentage of Respondents (%)</th>
</tr>
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<tbody>
<tr>
<td>Age range (yrs)</td>
<td></td>
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<tr>
<td>20-29</td>
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<tr>
<td>30-39</td>
<td>24.0</td>
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<td>40-49</td>
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<td>70+</td>
<td>1.4</td>
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<tr>
<td>Professional experience (yrs)</td>
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<tr>
<td>6-14</td>
<td>38.0</td>
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<tr>
<td>North</td>
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<td>18.7</td>
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<td>16.3</td>
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<tr>
<td>Highest educational degree attained</td>
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<td>Bachelor’s degree</td>
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<tr>
<td>Master’s degree</td>
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<td>Doctoral degree (PhD or equivalent)</td>
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<td>Certified Medical Publications Planner (CMPP)</td>
<td>4.8</td>
</tr>
<tr>
<td>Other</td>
<td>11.5</td>
</tr>
</tbody>
</table>
important” category. Thus, while the relative importance of items may differ among subgroups, the overall ranked importance is still high enough to warrant inclusion in examination design.

What’s Next?
Here are some of the next steps in our ongoing process.

- The first Commission Chair (Tom Gegeny) will remain a Commission member, and the Chair-Elect (Karen Potvin Klein) became Chair of the Certification Commission in October 2012 and will serve 2 years. In fall 2012, some current Commission members will have their terms renewed, and some new members will be appointed. Terms will be either 1 or 2 years.
- Using the information from the survey, the Commission will work closely with SMT to develop an outline for the examination and determine the relative weighting of elements within it.
- The formulation of test questions will require input from a diverse group of subject-matter experts. SMT will provide extensive training to the subject-matter experts on how to construct unambiguous test questions that measure relevant concepts and reflect competent day-to-day practice. By generating questions that link back to the examination content outline, we will ensure that all questions are fair (ie, relate to practice) and relevant (ie, are important to practice).
- During the item development and examination construction process, SMT follows strict security policies and procedures to ensure that access to confidential information is limited to individuals and entities authorized to use that information. All subject-matter experts will be required to sign affidavits of nondisclosure before participating in any item or examination development activities and will undergo rigorous security training.
- In the coming year, the Commission will define eligibility requirements for certification candidates, assemble a set of suggested review material that could be used to prepare for the examination, and determine an examination format.
- The Commission will continue to talk with sister organizations to identify “lessons learned” from those offering certification, include members of those allied organizations on the Commission as appropriate, continue to recruit subject-matter experts for composing test questions, and market the examination to medical writers outside of AMWA.
- The Commission will maintain regular communications with AMWA members through future articles in the Journal, updates on a dedicated area of the AMWA website, and other forms of communication. Reaching out to members at the chapter level is also a key part of our communication plan.

Closing Comments
The certification effort is extremely important for AMWA and the medical writing profession. AMWA has embarked on this process in a deliberate and evidence-based way, seeking input from a broad range of individuals. Not only will the survey results help AMWA improve its educational offerings but the results will have broader implications as well. By engaging practitioners across the profession to help define what is considered professional excellence, we will strengthen the profession and help ensure a solid skill set for medical writers of the future.

Please join us on this journey.

Acknowledgment
The Job Analysis Panel included the authors; David Clemow, PhD; Barbara Gastel, MD, MPH; Marianne Mallia, ELS; Lori Alexander, MTPW, ELS; Nancy Dew Taylor, PhD; Flo Witte, PhD, ELS; and Susan Krug, CAE. The authors thank the other members of the Panel and Certification Commission members Robert J. Bonk, PhD, and Sue Hudson for their review of the conference presentation and this article.

Author disclosures: The authors note that they have no commercial associations that pose a conflict of interest with this article.

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References
Edie Schwager
December 16, 1916-October 17, 2012

Edie loved words, and she loved the precise use of words. It seems strange, then, that there are simply not enough words to describe Edie’s contributions to AMWA and to all of our lives, and that the words that do exist are neither precise enough nor meaningful enough to convey the magnitude of those contributions. Edie was a unique treasure; as my Mississippi relatives would say, “they broke the mold when they made her.” She was mentor, friend, encourager, oracle, guide. She was, quite simply, Dear Edie, and all of us are the richer for having known her. I will miss her. Rest well, Dear Edie! You have earned it.

—Flo Witte
Winchester, KY

On October 17, 2012, AMWA lost its treasure when Edie Schwager passed away. Edie was well-known—and revered—across AMWA as Dear Edie, the wonderfully wise woman who answered our grammar and usage questions for decades, in the *AMWA Journal*, in her popular workshop, and around any table where AMWA members gathered.

AMWA mourns Edie’s passing, and many members have sent tributes that are included here, with more online. The tributes reflect Edie’s essence, and it’s also important to note her distinguished professional and AMWA career, although, as Flo Witte has said, “words alone cannot convey the magnitude of her contributions.”

Edie was born and raised in Trenton, NJ, and graduated from Trenton Central High School in the academic (precollege) program. She never made it to college, because of financial reasons, and instead worked as a legal secretary, first in Trenton and then in New York City. She met her future husband in New York, and they later relocated to Philadelphia with their two children, Michael and Karen. To earn extra money while her children were young, Edie typed dissertations and theses for students at the University of Pennsylvania. Edie did not simply type a student’s manuscript...no, Edie insisted that the student “sit down beside me to go over the paper.” She discussed changes that she thought the student should make. Although she didn’t realize it, she was a teacher, and an editor.

“I didn’t know I was an editor until a friend from the Hahnemann Medical School (now MCP Hahnemann University) told me that I was,” she said. That friend brought her onboard as an editor, and over the next 10 years, she edited 19 textbooks and several hundred scholarly papers.

Edie joined AMWA in 1964 and served two consecutive terms as president of the Delaware Valley chapter (1973 to 1975). She was the editor of *Medical Communications* (the forerunner of the present *AMWA Journal*), and an editorial consultant to the *AMWA Journal* since its inception.

Edie was recognized with AMWA Fellowship in 1975 and received the President’s Award in 1981. Two years later, she was honored with the McGovern Honor Lectureship, and in 1986, she received AMWA’s highest award, the Swanberg Distinguished Service Award. She was also the proud recipient of the Golden Apple Award in 1989.

In addition to her “Dear Edie” column in the Journal, Edie is best known for her “English Usage and Abusage” workshop, which she began leading in 1975. Over more than 30 years, Edie led her workshop—always filled to capacity—at the annual conference and chapter conferences around the country. In the early 1990s, she published *Medical English Usage and Abusage*, as well as *Better Vocabulary in 30 Minutes a Day*. She became a familiar sight at the AMWA authors booth at the annual conference, where she delighted members while signing their books.

Edie’s contributions to AMWA are unmatched. Her wit, wisdom, and warmth will be missed by so many of us who knew her and loved her. I had the privilege of working with Edie on the Journal for nearly 10 years. She was unique among Journal contributors in that she insisted that we review her column by talking to me on the phone rather than by sending a corrected file. My calls with her became a highlight of my editorship. Edie never started the calls with the “business”—always with the “pleasure”—and we would talk about our travels and well-being, with a sprinkling of her advice (“Nap whenever you can, dear.”). She was one of my strongest supporters, telling me I was the “best editor” she knew. Of course, she would scold me when a stylistic error made its way into an issue, but all was well immediately after she made her point. She always signed her e-mails to me with “L&K”—“Love and Kisses.” I miss that. I miss her.

—Lori Alexander
Orange Park, FL

December 16, 1916-October 17, 2012
My wife, Andrea, and I paid a Shiva call to Edie’s children, Michael and Karen. It was an inspiring experience for an inspirational woman. When we arrived, about 20 people were already there, and the rabbi was going around the room asking all who were there to introduce themselves and describe Edie in a word. When it was my turn I said I was carrying with me the love and affection of all AMWA members throughout the country, and especially in the Delaware Valley Chapter. Then I offered “fondly.” That’s the word Edie always used to sign her e-mails to me, and it always said so much to me beyond a mere salutation. Edie always made her words work hard and earn their keep.

About three-quarters of the way through the service, the rabbi asked people to share their stories of Edie. She began with Michael, who gave the most elegant and eloquent speech I believe I have ever heard in such a circumstance. He spoke of Edie’s many, many achievements. He talked about AMWA being the centerpiece of her professional life, and a great joy for her. He also spoke of the many challenges Edie faced and overcame, from losing her mother at age 8, to facing breast cancer, to her final days, which she faced with great strength, peace, and optimism. Even then, she considered herself lucky for all she had and dwelled not on what she had not. Edie was decades ahead of her time, delaying marriage and childbirth compared with her peers, traveling the world, embracing new experiences, learning to use a computer in her 70s (and better than many people much younger than her), writing her first book—Medical Writing Usage and Abusage—at age 80, and the list went on. Karen spoke next of Edie’s pioneering spirit and drive, about how she knew and loved everyone and everyone knew and loved her—from the many caregivers who helped her during the past 3 years since her stroke, to those who knew her as a fixture at Hymies, her favorite lunch spot. Even the person who delivered the mail each day to Hymies knew Edie and would come over to say hello. Edie’s picture hangs on the wall in Hymies.

The beautiful quilt that was made for Edie by Susan Siefert, depicting her many awards, was mentioned with great admiration. Andrea spoke of the times she met Edie at AMWA conferences, and how Edie embraced her with the same affection as she did everyone even though Andrea, as she puts it, can’t spell her way out of a paper bag. Another person spoke of Edie’s characteristic hello for people she adored, taking both of your cheeks in her hands and giving you a big smooch. How I’ll miss that! There were people there of all ages and walks of life: Edie’s grandchildren, whom she adored, the family of whom she was always so proud, friends and colleagues she touched so deeply and taught so fervently—even when she didn’t know she was teaching.

Edie taught us all again last night. She taught us about living a full, rich life, about taking chances and embracing change, and about recognizing how much we have to be thankful for each and every day. I am most thankful right now for having known her.

—Brian Bass
Robbinsville, NJ

Read more tributes to Edie in a Journal online exclusive at www.amwa.org.
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Sometimes opportunity takes its sweet time.

When I started my business, back in 2005, I was hired to write summaries of advisory board meetings. At these meetings, pharmaceutical companies present data or a research plan to a dozen or so physicians, who provide feedback. The summary writer attends the meeting, takes copious notes, and then goes home and writes up a summary.

What could be better? Back in 2005 my son was a baby, and I thought it was wonderful that someone paid me to leave my home, which smelled of dirty diapers and sour milk, and fly to a city like Chicago or Dallas, where I would stay in a clean, quiet hotel. As a bonus, the summary writing process wrapped up quickly and completely, unlike manuscript or regulatory writing, which goes on for months or years.

I soon discovered that some advisory board meetings were held overseas, in places like Switzerland. I was happy doing advisory board meetings in Dallas, but how much cooler would it be to go to Paris? So in 2007, I tried pursuing more advisory board work with the hope of being sent to an exotic locale. I put the word out to clients and placed advertisements in the AMWA pink pages (remember those?). I had lunch with colleagues who did advisory boards. I renewed my passport.

None of these tactics worked. Unfortunately, my campaign closely coincided with the international banking system’s fall into chaos. Even companies not directly affected by the recession cut back on unnecessary expenses—such as advisory board meetings. Not only did I fail to get international advisory boards, my domestic advisory board business dried up.

So, some years I did one advisory board meeting, some years, none. My dream of doing international advisory board meetings stayed in the back of my mind as my business grew through manuscript writing and editing and as my son grew out of diapers and into Star Wars underwear and finally Shaun White boxers.

And then, in June of this year, I received an e-mail from an old client. Would I like to do an advisory board meeting in Lima, Peru? My answer: of course! By then, my son had turned 7, and the prospect of travel to Latin America—let alone sightseeing in Lima—was very enticing. I decided to fly in to Lima two days early so I could enjoy the local sights.

Unfortunately, the travel nurse I saw to update my vaccines seemed delighted to describe all the possible perils of traveling to a developing country. She warned against having a money pouch or necklace around my neck because someone could grab it and choke me. She said I needed emergency medical evacuation insurance in case of catastrophic injury. And she gave me a report from the American consulate in Peru, which described recent alleged crimes against Americans. The crimes included kidnapping, rape, and murder. Americans were warned to not go anywhere alone.

That’s what I would be: alone. For two days. In a place where I knew no one and didn’t speak the language. Afraid the trip would be the death of me, I told my husband I had made a huge mistake. How could I leave my son without a mother? My husband reminded me that I would be staying in a Sheraton next to a Starbucks. With some common sense on my part, I would be fine.

Turns out he was right. During my solo time in Lima, I got to put my hand in the Pacific Ocean. I strolled to El Parque Del Amor, a beautiful park with tiled walls adorned with sayings about love and a giant adobe statue of a man and a woman lying down in an embrace. I sampled the local fruit and ate two cherimoyas without getting sick.

And I went to my meeting, came home in one piece, and wrote my summary.

It would be fun to do another international meeting. But who knows whether I will? A part of me would like to think that the seeds I planted in 2007 led to my trip to Lima this year. Was that wish connected to this opportunity? Maybe. Maybe not. But at least I was ready when the opportunity arrived.

Jennifer King, PhD, ELS, is president of August Editorial, Inc, Durham, NC. Her e-mail address is jking@auguesteditorial.com.
The authors of a recent study identified “spin” in nearly half of press releases (47%) and news articles (51%) related to reports of randomized controlled trials. Spin was defined as specific reporting strategies—either intentional or unintentional—that emphasize the beneficial effect of the experimental treatment. The authors used bivariate and multivariable analysis to assess the relationship between spin and many factors, including the journal type, funding source, sample size, type of treatment (drug or other), and others. In multivariable analysis, the only significant factor associated with spin in press releases was the presence of spin in the abstract conclusion of the article (relative risk: 5.6; 95% CI, 2.8–11.1; p<0.001). This significant relationship is of concern, given that 40% of the 70 articles had spin in the abstract conclusion. The study, “Misrepresentation of Randomized Controlled Trials in Press Releases and News Coverage: A Cohort Study,” by Yavchitz et al., can be found at www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001308.

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# INTRODUCTION TO THE ENDOCRINE SYSTEM*

## PART 1: BASIC CONCEPTS AND ANATOMY

By Jacqueline Wu, PhD,* and Joanne M. McAndrews, PhD**

*Owner and medical writer, Castle Peak Medical Writing, Tucson, AZ, and **Freelance medical writer, St. Louis, MO

## APPENDIX. Online Information, Including Illustrations, for Endocrine Glands

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<th>Endocrine Gland</th>
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Medical writers are uniquely positioned not only to inform the public of health advancements, but also to engage their audience through stories to help people gain a greater perspective, says Dr Neal Baer, who received AMWA’s John P. McGovern Award and presented the keynote address at the 2012 annual conference.

As a television writer, Dr Baer tells stories to offer templates for viewers to ponder from the vantage point of their own experiences. He says he writes television scripts on controversial medical and public health issues, such as AIDS and childhood immunizations, because these medical and public health topics are in the “day-to-day struggles of our lives.”

Medical professionals also tell stories. During his medical training, Dr Baer found the key to caring about patients was “to learn their stories” as each patient’s narrative is unique. A good story, however, does not necessarily present all of the details of a patient’s illness. For example, as a third-year medical student, he treated a 65-year-old patient who awoke during the night with chest pain. As the patient told the story, Dr Baer learned that the patient had experienced increasing shortness of breath during runs that led to a myocardial infarction (MI). However, upon examination, the patient had no congestive heart failure signs. So, he checked the patient’s medical records, and the patient had a normal electrocardiogram. Puzzled, he decided to order the medical tests that helped him diagnose the patient with aplastic anemia, the medical condition that ultimately led to the MI. This patient taught him to look for the “twists and turns in the stories.”

According to Dr Baer, “Being a good storyteller means connecting with one’s patient.” Incomplete stories can lead to poor outcomes. Moreover, he has found that the best doctors are great storytellers.

Will anyone pay attention to the stories we tell? “The answer is yes,” he said. He further elaborated, “We make sense of our lives by telling stories.” According to Dr Baer, we conduct private storytelling when we discuss our work with colleagues.

The stories that he has told on television are what Dr Baer calls public storytelling. These stories are personal, dramatic, and, he hopes, compelling. Medical writers present facts and figures. Then, another person may read the data and present a counterview—a personal, possibly non-medical viewpoint. To demonstrate this point, he responded to the anti-vaccination movement through a Law & Order: SVU episode, “Selfish.” The episode explored the question of what a person’s responsibility is to the community through a story line in which a young child dies after contracting measles from an unvaccinated child.

According to Dr Baer, “Stories are the currencies of our lives.” He says a story should be told, even if it is controversial. Viewers become engaged as they watch the television characters “duke it out.” If the show is particularly moving, the viewers may begin to think of the presented issues in a slightly different way. For example, he is passionate about stopping gun violence. He showed a segment of the Law & Order: SVU episode “Infected,” which was inspired by an article he had read in Science.¹ The episode

¹ The episode was inspired by an article in Science. The article was published in Science, 2010, 329(5993):1139-1143. The patient’s story was adapted from his own experience.
Presented data from the article that indicated children exposed to gun violence are 2 to 3 times more likely to commit serious violence. The episode associated gun violence with an infectious disease. “Violence is the disease; guns are the virus,” an SVU character says. “And we have an epidemic on our hands.”

To portray how public storytelling can help us in our own lives, Dr Baer discussed an ER episode that referenced the association between human papilloma virus (HPV) and cervical cancer. Before and after the ER episode aired, the Kaiser Family Foundation surveyed ER viewers to determine if they knew of the HPV/cervical cancer link. Moreover, the survey results showed a statistically significant increase in the proportion of viewers who were aware of HPV and could provide an accurate definition of HPV based on watching this episode of ER. The survey also determined the following points:

• 53% of viewers said they learned important health issues from ER.
• One-third of viewers obtained information that helped them with their family.
• One-seventh of viewers discussed what they had seen on ER with a doctor/health care provider.

Furthermore, with the Internet, medical writers have more tools to help with public storytelling. “The online world is a rich resource for your stories,” he says. To illustrate, he presented BubbleTweet (available at www.bubbletweet.com), a short (60 seconds or less) pop-up video that can be posted to Twitter. He has used BubbleTweet to help augment television show viewing. He played one such tweet he created for the Law & Order: SVU episode, “Witness,” about violence against women in Congo, which is available at bbltwt.com/chuk2. Additionally, the episode received attention through a Huffington Post blog item coauthored by SVU actress Mariska Hargitay.3

Importantly, these methods provide actionable steps for viewers to learn about public health issues and to help in their lives and the communities. In conclusion, Dr Baer said one can “harness storytelling to produce social change.”

Dr Julie Phelan is president of Biomedisys, Inc, a biomedical communications and strategy consulting boutique in Chicago, IL.

References

Special Feature:
Listen to the Swanberg Address of Susan Aiello, DVM, ELS, while viewing her accompanying slide set.
In her presentation “Document Quality Control: A QCer’s View of the World,” Dianne De Jesus described herself as a technical editor who performs quality control (QC). She began her discussion with why regulatory documents need QC. When a writer has looked at a document for too long, a second set of eyes can catch errors. There is also a need for a new and objective look at documents in which there are potentially conflicting comments from multiple reviewers; part of her review is to make sure all comments are incorporated.

When she first started her job at ICON, she worked entirely in hard copy, but now that she works from home, she works with electronic copies. Her process, as she described it, is to “ensure a certain level of quality within a clinical document prior to delivery.” She QCs many types of documents, including clinical study reports, new drug applications, and integrated summaries of safety. Her two types of QCs are a content QC, which includes verification of scientific data (via a cross check between source documents and the working documents) and a technical editing QC, which includes style, formatting, grammar, usage, and spelling.

The writers provide a narrative map indicating the locations of the sources to help her perform the needed cross checks. In the process she currently follows, she conducts a document QC at three different stages: when it is a shell, at first draft, and at completion. In her experience, the level of QC needed decreases as a document moves through the process.

She walked through the check-list she follows via her PowerPoint slides. Her list includes many types of checks: “glaring mistakes/issues,” grammar, punctuation, consistency, compliance with style guide. She also performs many types of checks to compare different parts of the document: the abbreviations list against the synopsis, the schedule of assessments against the study activities, in-text tables against data source, in-text tables against data within the text, the table of contents against the text in the document. She also checks all the references for the tables and figures, checking the hyperlinks as needed.

Other documents she shared in her PowerPoint were her QC request form (which included information on the project, the deliverable, who is requesting the review, the due date, and additional directions or instructions) and her review tracking spreadsheet, which is provided to the company’s Quality Assurance team. She mentioned that the QA team audits the process from start to finish, including her participation; QA checks all of the documentation given to her, the checklist she uses to conduct her QC, and all of her edits and comments. For this reason, she is limited in her review to what the writer requests.

Despite the fact that she is responding to requests from writers for her assistance, she does have rejection criteria. If there are a certain number of errors on the first page or incomplete content, she can return it without doing the QC.

Many in the audience were surprised to hear that she did not use track changes to make corrections, even when completing a technical editing QC; all of her edits are documented in Microsoft Word’s comment feature. Though medical writers are not required to make her changes, she can verify whether they do through subsequent reviews.

Kelly Schrank works from her home near Syracuse, NY, as a medical editor for Med Communications.
FALSIFICATIONS AND RETRACTIONS

Moderator and Speaker
Andrea Gwosdow, PhD
President, Gwosdow Associates Science Consultants, Arlington, MA

Speakers
Rebecca Lew, PhD, CMPP
Senior Medical Writer, ProScribe Medical Communications, Melbourne, Australia
Kim E. Barrett, PhD
Dean of Graduate Studies, University of California, San Diego

By Kelly A. Keating, PhD

“Something doesn’t seem quite right here.” “This seems familiar.” “Why does the writing suddenly improve in this paragraph?” “Is the image in this figure distorted?” If as a medical writer and editor you have ever found yourself with these thoughts running through your head and then followed up by diplomatically making author inquiries, you can add “ethical detective” to your list of skills. Each speaker in this session offered advice on how to investigate and analyze issues such as these that you may encounter and that can contribute to a potential article retraction.

Andrea Gwosdow, PhD, quoted the Merriam Webster Dictionary definition of retraction as “to draw something back in.” In publication terms, a retracted article is one that has been removed from Medline after a journal issues a retraction notice. The journal’s editor makes a retraction decision based on either error by the author or journal, or on the more serious reason of author misconduct. The journal retraction notice should explicitly state the retraction reason.

The speakers defined author misconduct as plagiarism (using someone else’s text verbatim for example, or even your own text as self-plagiarism—intentional or not) and falsification or fabrication of data and reporting it (changing or making up data to improve the results). Each speaker emphasized that retractions because of author misconduct matter for ethical reasons and because retracted papers continued to be cited in the literature, potentially leading to a false impression of the reproducibility or impact of a finding and biasing meta-analyses that include the data.

Kim Barrett, PhD, and Vice-Chair of the Publications Committee for the American Physiological Society (APS), pointed out, “Intellectual honesty is an essential tenet of scientific life,” and science is an enterprise based on trust. Violation of that trust betrays the authors’ colleagues, the journal, and the public, and after all the public’s taxpayer dollars may have funded that research.

Reasons for Retractions
Rebecca Lew, PhD, CMPP, in 2011 coauthored an article that quantified the factors contributing to retractions from Medline between 1966 and 2008. The authors found that of 463 retractions, almost half (213) were because of author misconduct, and the most common misconduct reasons were plagiarism and falsification or fabrication of data.

Falsification can include digital manipulation of images such as blots or micrographs. Barrett cautioned that an author should not move, remove, introduce, obscure, or enhance any feature within an image. For example, an image of a blot should appear in an article exactly as captured in the laboratory, blemishes and all. Barrett said that manipulation of images, whether the author knows if image alteration is allowed or not, is the most prevalent type of misconduct seen for manuscripts submitted to APS journals. She reported that the actual number of misconduct cases investigated by APS each year among about 8000 manuscripts received is small; APS projects there will be 161 investigations in 2012. Still, APS has observed an increasing number of cases, so there is a need to be vigilant. Barrett cited the risk factors in the publishing environment that are associated with violations of ethical policies of a journal: author inexperience/lack of mentoring on appropriate standards, the availability of software tools for figure manipulation, and the increased competition for positions and funding.

Advice for Medical Writers
How can medical writers help their clients avoid retraction? Gwosdow’s advice was to work in a collaborative spirit with clients to educate and inform, and thereby head off any tendency toward plagiarism or falsification. Sometimes the misconduct can be unintentional—a graduate student who is contributing data may not know that it is not permissible to erase small bits of debris or noise in an image—and an “innocent until proven guilty” approach is the most diplomatic. Medical writers should tread carefully and respectfully when corresponding with an author, asking questions without accusing to try to get to the bottom of any suspected misconduct.

Lew advocated for the medical writer to not perpetuate the problem. That is, be sure not to cite a retracted article. Retracted articles can be identified in PubMed by doing an advanced search, selecting “retracted publication” as the publication type, and combining with a general key word related to your manuscript to check that none of the manuscript’s cited articles comes up in the search.

Medical communicators can use a checklist to help them handle a difficult situation the “RIGHT” way—a five-step model developed by AMWA ethics workshop leaders for
use by professional medical communicators:

- Recognize the ethical situation.
- Investigate the facts and assumptions.
- Gauge the situation and decide.
- Handle the situation and implement the decision.
- Tailor the decision (evaluate and revise).

Gwosdow also suggested some questions to ask yourself as you encounter ethical issues:

- Who is involved in the ethical situation? Who will be affected by the decision?
- What are the relevant principles in the AMWA Code of Ethics?
- What are the conflicts of interest?
- What are all the possible courses of action and likely consequences of each?
- Who can or should help?
- What lessons can be learned?

Using this checklist and asking yourself these questions may help you as a medical writer to educate your clients and help them avoid unintentional ethical lapses, or conversely to detect intentional ethical wrongdoings and decline to work with the client any longer. Lew suggested that medical writers can act as the final gatekeeper and by their diligence help protect themselves, their clients, and journals, and contribute to accuracy in the medical literature.

Kelly A. Keating is a Science Editor/Medical Writer at the Pharmaceutical Research Institute, Albany College of Pharmacy and Health Sciences, in Albany, NY.

References


Resources


SO YOU WANT TO WRITE A BOOK

Speakers
Debra Gordon, MS
President, GordonSquared, Inc,
Williamsburg, VA
Alisa Bowman
Writer, Emmaus, PA

By Kelly Schrank

In introducing herself and her co-presenter, Debra Gordon was quick to point out that their session, “So You Want to Write a Book,” would be focused on nonfiction. She and Alisa Bowman have contributed to more than 50 nonfiction books in the past 15 years. Gordon began the presentation with her 10 myths of writing a book (see sidebar). One big myth is that you’ll make a lot of money, and Gordon dispelled this by saying that writing a book is not an easy or quick way to make a living. The two of them have found, however, that providing your services to an author can be more lucrative.

One such service is writing book proposals on behalf of an expert on a particular topic. For a 50-page proposal that includes the table of contents and some information on potential content, you may be able to negotiate an $8,000 fee. If the proposal were accepted by a publisher, and you wrote the book with the co-author, you might be able to make $70,000 for about 5 months of work. This is much better than the royalties you might receive if you wrote a book yourself. Both presenters mentioned throughout the session that, in contrast to the peer-reviewed medical literature, ghostwriting is an accepted practice in nonfiction book publishing, especially in bestsellers. Gordon advised attendees to get an agent; even after paying 15% to the agent, you will make more than if you had negotiated the deal yourself.

Other practical information that came out of Gordon’s discussion included the importance of setting goals for the project by chapters (for example, write a 6,000-word chapter each month), the evolution of self-publishing from “being something
you'd be embarrassed to tell your mother about to being quite lucrative,” and the vital skill of marketing. It doesn’t matter how cool your topic is or how good of a writer you are if you don’t know how to sell the book.

Gordon also discussed the elements of a book proposal, with some tips to make them more effective:

1. Overview: must sell the idea (ie, why the book should be written, why you’re the person to write it, and what your “platform” is).
2. Table of contents (TOC): must have enough detail to sell the book.
3. Sample chapter: may be optional if the TOC is detailed enough.
4. Marketing plan: must show how you are going to market your book, ideally with the help of a publicist you hire.
5. Description of your audience: shows that you have one.
6. List of some of your competitors: shows that there is already a market for the type of book, as publishers resist going into completely new genres.
7. Names of others willing to write a foreword or back cover blurb for your book: shows that you have connections and can attract others to your project.

Alisa Bowman began her part of the presentation with a story of moving from one dream job to another. She was a runner writing for Runner’s World, where she said she was paid to run marathons. Now she is a full-time writer working only on word-of-mouth advertising. Her presentation was based on her past mistakes, and was titled “How to Not Write a Book in 13 Easy Steps.” In discussing why you should not spend your advance on a home improvement project, she explained how advance payments are made. The advance is paid in installments, usually three or four, depending on whether the book will be published first in hard cover or immediately as a paperback. One check comes after all the paperwork for the deal is signed (which often takes substantially longer than you think it should), another check comes after the manuscript has been submitted and accepted by the publisher (right before publication), and then another check comes after publication. If there is a hard cover and paperback, there is one check after hard cover publication and another after paperback. If you are thinking of publishing a book with graphics or an index, the costs for having these prepared also comes out of the advance.

It is especially important to deliver a manuscript at the agreed-upon length. Bowman explained how there are professionals at the publisher who decide the pricing for your book based on its length, the competition, and the price points that will entice your audience. If the publishing professionals say you need to write a 150-page book for your audience and price point, then you need to provide a 150-page book. If you don’t, the publisher could cancel the deal.

In keeping with Gordon’s advice that it’s not enough to be a good writer, Bowman mentioned the importance of marketing, entrepreneurship, and interpersonal skills in being able to work as a freelance book author or co-author.

Questions at the end of the session generated even more advice. When asked how to break into the field, the speakers suggested reaching out to people you work with to see if anyone is interested in writing a book. If someone you know is doing an interesting study, ask the author if he or she would like to write a book with your help. Bowman also discussed how easy it is to publish an eBook. Amazon, for example, has tutorials to walk you through how to put an eBook on its site (kdp.amazon.com/self-publishing/signin). Or you can use your own website to post the eBook, then find affiliates to help you promote it.

Kelly Schrank works from her home near Syracuse, NY, as a medical editor for Med Communications.

Glossary

Affiliate: Someone that helps you promote your book through their communities (via a blog, website, Facebook, Twitter, or other social media); if the promotion garners a sale, you pay them a set fee for each sale.

Author Platform: From Christina Katz in Get Known Before the Book Deal

“A platform communicates your expertise to others. It includes your Web presence, any public speaking you do, the classes you teach, the media contacts you’ve established, the articles you’ve published, and any other means you currently have for making your name and your future books known to a viable readership.”

Debra Gordon’s 10 Myths of Writing Nonfiction

1. You will make lots of money.
2. You should write the book first, then find a publisher.
3. You don’t need no stinkin’ agent.
4. A cover letter and a table of contents is all you need to sell your book to a publisher.
5. Ghostwriting is verboten.
6. It’s OK to write the proposal for free for your author; if the book sells, then you’ll be paid.
7. Doctors/co-authors are easy to work with.
8. You should block off a year to write a book.
9. All you need to sell your book is great content.
10. It’s easy to sell a book these days.
The 2012 recipient of the Harold Swanberg Distinguished Service Award is Susan Aiello, DVM, ELS. This prestigious award, named for one of AMWA’s founders, is presented to “an active member who has made distinguished contributions to medical communication or rendered unusual and distinguished services to the medical profession.”

Susan’s contributions to medical communication are many, and her selection for the Swanberg Award particularly recognizes her major contribution to developing the new AMWA curriculum. She has also been active in the Board of Editors in the Life Sciences (BELS), currently serving as its president. As editor of The Merck Veterinary Manual, a veterinary medical textbook, she has contributed substantially to communication in veterinary medicine.

Susan was selected for the Swanberg Award this year because she played a leading role in developing and establishing AMWA’s new curriculum, as well as in developing the science certificate that preceded the new curriculum. Providing “educational resources” in support of excellence in medical communication is an important part of AMWA’s mission, and our educational program is an exceptional resource. In 2010, AMWA established an updated and greatly expanded certificate program. Susan chaired the Committee on Expanded Certificate Program, and in a nomination for the Swanberg Award she is credited with having the “foresight, dedication, and perseverance” needed to organize a new curriculum and bring it to fruition.

In 2000, after she had been an annual conference roundtable leader for several years, Susan led one credit workshop; in 2009, she led four credit workshops. She has also led workshops at chapter conferences and on-site workshops. She has taught about 10 different workshops, some of which she developed. In 2005, Susan became an AMWA Fellow and received the Golden Apple Award for excellence in education. From 2007 to 2009, she was Annual Conference Workshop Coordinator.

Susan has served AMWA in many areas besides education. Her sense of humor and her creativity and vision have long distinguished her as an AMWA leader. In the Swanberg Committee’s discussions, “charisma” was mentioned as one of her qualities. She has served on the Executive Committee as Awards Administrator twice and on numerous other AMWA task forces and committees, including ones to award student scholarships and medical book awards. At annual conferences, she has coordinated klatches and roundtables, been an open session panelist, and led water aerobics. She has also been a proofreader for the AMWA Journal.

Susan has taught communication courses in other settings besides AMWA, including the Writers’ Workshop for the Harvard Medical School’s Department of Continuing Education.

The story of how Susan transitioned from veterinary practice to being a full-time medical communicator is told in a member profile in the AMWA Journal. She developed extraordinary skills in publications management when she worked for Merck & Co., Inc., from 1988 to 2001. She managed the print and electronic publication of The Merck Veterinary Manual, which had more than 400 authors and peer reviewers, from development to production. An Editor in the Life Sciences since 1991, Susan has been a member of the BELS Executive Council since 1999. She became president of the organization in 2011.

As a freelance editor and writer from 2001 to 2011, Susan edited medical textbooks and health-related trade books, and she wrote and edited the medical content of websites on geriatrics and veterinary medicine, in addition to completing many other projects in writing, editing, and teaching. In 2011, she resumed editorship of The Merck Veterinary Manual.

In her reply to the letter notifying her that she had been selected for this award, Susan wrote, “AMWA has been a significant part of my life for many, many years…To be recognized for contributions to the profession is truly over the top!”

The 2012 Swanberg Award Committee included Barbara Gastel, MD, ELS(H); Douglas Haneline, PhD; Larry Liberti, MS, RPh; Marianne Mallia, ELS; and Michele Vivirito.

Reference
Each year, AMWA may recognize up to three members for significant contributions to the goals and activities of the association. AMWA Fellowships are awarded to active members, typically those with more than 5 years of service and activity. This year, the Fellowship Committee nominated three outstanding members to the AMWA Board of Directors to consider for Fellowship. All three candidates were awarded this honor because of their contributions and activities that have furthered the mission and work of AMWA.

TAMARA BALL, MD
Tami joined AMWA in 2004 and immediately became involved nationally as part of a chapter revitalization task force. This work coincided with her substantial efforts to revive the Michigan Chapter, which was at risk (at that time) of becoming defunct. She went on to serve as that chapter’s president in 2007-2008. In the relatively short time since she joined AMWA, Tami has made remarkable contributions both nationally and at the chapter level. Tami has been a session presenter at AMWA’s annual conference, including leading workshops and breakfast roundtables. In addition, she has served several terms on the Executive Committee (EC) and has been a member of many committees in areas such as annual book awards, educational technology, and leadership training.

FAITH REIDENBACH, ELS, CMPP
In the little more than a decade since she joined AMWA (in 2001), Faith has made an indelible mark on AMWA through noteworthy contributions in the areas of publications, website/technology (including the Freelance Directory), and the annual conference. She has served on the EC in the departments of Publications, Web and Internet Technology, and Awards. Particularly in the areas of publications and technology, Faith has undertaken challenging projects. A prime example of this is Faith’s work in 2010 to establish the AMWA Journal Charter, which clearly delineates the roles and responsibilities of the AMWA Journal and its parent organization/publisher. The charter now serves as a cornerstone document for AMWA’s flagship publication. Faith has also contributed regularly to the AMWA Journal itself, has led sessions at the annual conference, and served on AMWA’s Certification Task Force in 2009–2010 and the Constitution and Bylaws Committee in 2011–2012.

CHRISTINE WOGAN, MS, ELS
An AMWA member since 1989, Chris has distinguished herself through long-time service in the Southwest Chapter, first as treasurer and later as president. Nationally, Chris has distinguished herself through numerous activities at the annual conference and her service on the EC (Awards Administrator, 2010–2012), as well as 3 years on the Budget & Finance Committee. She has also served as a peer reviewer and article contributor for the AMWA Journal. In 2010, Chris was honored with the President’s Award to recognize her contributions to AMWA.

The 2012 Fellowship Committee members included Kevin Flynn, MA; Bart Harvey, MD, PhD; Donna Miceli, BS; Peggy Robinson, BSc, ELS; and Victoria White, MA, ELS.
Peggy Boe, RN, is this year’s recipient of the Golden Apple Award, the highest honor an AMWA workshop leader can achieve.

Established in 1986, this prestigious award honors workshop leaders who have demonstrated consistent excellence in teaching in AMWA’s educational program. Each year, the Education Committee selects the Golden Apple winner after a thorough review of the teaching records of all workshop leaders who meet the criteria for the award. To be eligible, a workshop leader must have taught at least 12 workshops at AMWA’s annual or chapter conferences and maintained an overall score of 4.4 (out of a possible 5.0) on participants’ workshop evaluations for all workshops he or she has taught. Other criteria considered include the difficulty of the content and the diversity of workshops taught, the number of new workshops developed, and the number of years the leader has volunteered to teach these workshops.

Since 2004, Peggy has taught 26 workshops at annual and chapter conferences throughout the United States. The committee was particularly impressed with the number of credit workshops Peggy has developed—five—two within her first 3 years of membership in AMWA. The committee also noted the level of difficulty of the workshops and their complex, detailed nature; for example, Electronic Technical Document, IND in eCTD Format, Summarizing Clinical Efficacy Data for an NDA (and its companion, Summarizing Clinical Safety Data for an NDA), and Ethics of Communicating Regulated Drug Development Activities. Her workshops form a core portion of AMWA’s Regulatory and Research Specialty Certificate program. One committee member summed up Peggy’s contributions most aptly: “Peggy’s generous sharing of her expertise and personal experience with regulatory documents and processes has benefited all those who’ve taken her workshops and greatly strengthened AMWA’s educational program in the regulatory arena.”

Developing and teaching workshops have not been Peggy’s only contributions to AMWA. She has also generously shared her expertise and experience as a speaker for open sessions and a breakfast roundtable leader at annual conferences, and as a regular contributor to the AMWA Journal, for which she serves as section editor of Regulatory Insights.

In another life, Peggy was a registered nurse with specialty certification in perioperative nursing. About 15 years ago, she entered the medical writing profession, gaining diverse experience in regulatory medical writing, editing, training, consulting, and entrepreneurial business management. She is currently the associate director of medical writing for Boehringer Ingelheim.

On behalf of AMWA, the Education Committee is honored to add Peggy Boe’s name to the list of distinguished recipients of the Golden Apple Award. We thank her for her outstanding contributions to AMWA’s educational program.

The 2012 Golden Apple Award Committee included Susan Aiello, DVM, ELS; Jenny Grodberg, PhD, RAC; Cindy Hamilton, PharmD, ELS; Sue Hudson; Marianne Mallia, ELS; Jennifer Maybin, MA; Sharon Nancekivell, MA (chair); and Karen Steinhilber, MLS.

The AMWA President’s Award is presented each year to a member who has made significant contributions at the chapter or national level and has never served on the Executive Committee. AMWA’s 2011-2012 President Barbara Snyder selected Barbara Zimmerman, PhD, to receive the 2012 President’s Award in recognition of her contributions to the Rocky Mountain chapter (serving multiple terms as secretary and president), to the annual conference (as a roundtable leader, Coffee Klatch leader, open session chair), and to AMWA on the national level (serving multiple terms as a delegate to the Board of Directors, and participating on several task forces and committees).
Alyssa Wu-Zhang, a doctoral student at the University of California, San Diego, is the recipient of the 2012 Annual Conference Student Scholarship sponsored by University of the Sciences in Philadelphia. The scholarship provided Alyssa with funds to cover the costs of attending the annual conference and participating in three workshops. The scholarship recipient was honored at the Sablack Awards Dinner at the conference.

Alyssa’s interest in medical writing stems from a deep appreciation for the beauty that lies in the order and objectivity of science and her innate affinity for writing and editing. A PhD student in biomedical sciences, Alyssa originally wanted to become a professor. However, she later realized that what had attracted her most to the PhD program was not doing research but rather achieving scientific clarity and mastery of knowledge at the level of a professor. Through her experience in graduate school—in research, in teaching, and in communicating science to other scientists, whether orally or in written form, formally or informally—Alyssa realized that, despite having achieved a fair amount of success in bench research, her interests really lie in applying her scientific expertise in medical communication. To further explore her interest and talent in this field, she applied for and won a year-long National Science Foundation graduate fellowship in science, technology, engineering, and mathematics education, during which she developed a novel, inquiry-based high school biology curriculum by using key scientific concepts from her thesis research. She also gained experience in science editing as a contract biomedical subject-expert editor for American Journal Experts. Now, as she is poised to defend her thesis, it has become clear to her that a career in medical communication would make a wonderful marriage of her background in science and her talent for writing and editing.

Alyssa first encountered AMWA on the Science Careers website of the journal Science, where AMWA was listed as a professional society under “Careers in Medical Writing: Resources.” Then, at a local life sciences networking event, a medical writer advised Alyssa to join AMWA after learning about her interest in medical writing. Alyssa joined AMWA as a student member this past spring, and when she learned about the scholarship from the AMWA Conference Connector, she decided to apply. “I realized what a great opportunity attending the conference would be for me as a young scientist who wanted to launch her medical writing career,” Alyssa says. Also, “being a student, I was not sure I could afford to attend the conference and pay for workshops, so I decided to apply to the scholarship and see whether that difficulty could be overcome,” adds Alyssa.

Alyssa was very grateful when she learned that she had won this year’s student scholarship. “If I had not received this scholarship, I don’t think I would have been able to attend the conference,” Alyssa says. She viewed the AMWA conference as providing unparalleled opportunities to build an extensive network of peers, to learn from experienced colleagues, and to participate in workshops for credits toward an Essential Skills certificate. To this end, Alyssa signed up for three Essential Skills workshops: Sentence Structure and Patterns, Punctuation for Clarity and Style, and Effective Paragraphing. She also planned to purchase the newest self-study module, Tables and Graphs.

Through the AMWA conference, Alyssa sought to expand her understanding of the field and jumpstart a rewarding career in medical communication. After graduation, Alyssa would like to become a medical writer in the pharmaceutical or biotech industry. She is particularly interested in applying her advanced scientific training to writing about complex clinical trial data. She believes that she would enjoy a project management position in which she can collaborate with many different people in a company to help shepherd a manuscript from scientific conception to submission.

The Annual Conference Student Scholarship Committee included: Mary Whitman, PhD, Beth Ann Garni-Wagner, PhD, Karen Potvin Klein, MA, ELS, Kelly Keating, PhD, and Lili Fox Vélez, PhD.
2012 ERIC W. MARTIN AWARD WINNER: JOSHUA TOMPKINS

By Paul Tom* and Leslie E. Neistadt, ELSb

*Intern, The Hughston Foundation, Columbus, GA, and bMember of the Eric W. Martin Award for Excellence in Medical Writing Committee

The Eric W. Martin Award honors excellence in medical writing; it is given in recognition of outstanding articles that were written and published by members of AMWA in the previous year. This year, one author won the award for articles submitted in the professional (medical) audience category and the category for the public or health care consumer.

Joshua Tompkins is a veteran science and health journalist whose work has appeared in The New York Times, the Los Angeles Times, Popular Science, Men's Journal, and other publications. Tompkins is also a medical student. His winning articles about this time in his life—Money for Nothing? The Problem of the Board-Exam Coaching Industry, and Confessions of a Middle-Aged Medical Student—were the highest scoring entries in both categories.

Following is an interview with Tompkins.

Q: What inspired you to go to medical school? Why did you decide to attend medical school at age 38?
A: Writing about medicine made me want to be a part of it, and I put off the decision for years. I wasn’t familiar with the postbaccalaureate programs available for older applicants, but they offer the necessary courses and application advice.

Q: What is the most difficult part of attending med school?
A: The hours are horrendous, the academic requirements are intense, and you need plenty of energy to carry you through the 40 to 80 hours per week. In the hospital, the anxiety of avoiding mistakes keeps you alert.

Q: What inspired you to go to medical school in your 30s, what would you say?
A: I would tell them to be ready because it is 10 times harder than they can imagine. You’re jumping through hoops, volunteering, and doing research. This takes time and dedication to accomplish, which means the only thing harder than medical school is probably joining the military. You will be physically and mentally tired all the time. Then, applying for residency is like applying for med school all over again. You have to deal with letters, interviews, and constantly being evaluated in a highly competitive atmosphere.

Q: Is medical school what you expected?
A: I expected most of it. I became fascinated with gross anatomy but started to despise it because you’re hunting for tiny, difficult-to-find anatomical structures. I’m not good at dissection and felt frustrated when professors would peer into my team’s cadaver and pinpoint the structures so quickly.

Q: Why did you choose psychiatry?
A: I chose psychiatry because I always enjoy talking with people and because nothing intrigues me as much as human behavior. My favorite character on M*A*S*H was Dr. Sidney Freedman, a psychiatrist, who would help people feel better by conversing with them.

Q: How long have you been writing about science?
A: I was an editor at Los Angeles magazine for many years and did a little of everything. After that, I became a freelance writer specializing in science and medicine.

Q: Will you open your own practice?
A: I’m going to stay in academia. A private practice is appealing, but it may be a little isolating. I’ll be a resident for 4 busy years, but I’ll continue writing, and my writing will now be much more informed.

Q: What do you do in your spare time?
A: I don’t have much spare time, but I read anything nonmedical or watch Frasier reruns when I get the opportunity. It’s a well-written, funny program that shows an overeducated windbag and his brother—both psychiatrists, by the way—making fools of themselves.

Q: If a fellow journalist were to ask you for advice about attending medical school in your 30s, what would you say?
A: I would tell them to be ready because it is 10 times harder than they can imagine. You’re jumping through hoops, volunteering, and doing research. This takes time and dedication to accomplish, which means the only thing harder than medical school is probably joining the military. You will be physically and mentally tired all the time. Then, applying for residency is like applying for med school all over again. You have to deal with letters, interviews, and constantly being evaluated in a highly competitive atmosphere.

Q: Is it worth it in the end?
A: It is worth it despite the constant fatigue and frustration, but I sometimes ask “Now why did I do this?” However, all I need is a good night’s sleep and I’m back to my old self.

The members of the Eric Martin Award committee included: Norman Grossblatt, ELSD(D), Katharine O’Moore-Klopf, ELS; Leslie Neistadt, ELS; and Christine Wogan, MS, ELS.
Eight books were honored in the 2012 AMWA Medical Book Awards competition. Following are reviews of the first-place winner in each category.

First Place, Physicians

*Mayo Clinic Gastroenterology and Hepatology Board Review, 4th edition*
Stephen C. Hauser, editor

This guide is intended for medical students, interns in internal medicine, and practicing physicians who would like a practical review of their knowledge of gastroenterology and hepatology. It is also valuable for medical writers who need background information for writing in these fields.

The book covers the basic subspecialties in the field. Included are sections on esophageal disorders; stomach conditions; the small bowel and nutrition; colon, liver, pancreas and the biliary tree diseases; and some pertinent miscellaneous disorders. The writers of the seven different sections are members of the faculty at Mayo Clinic and are recognized specialists in these areas.

In evaluating this book, the members of the Medical Book Awards committee raised the question: Does a textbook have to be boring and laden with complex sentences that make it incomprehensible? We all agreed that this book is very readable and interesting and that it meets the high standards of both writing and production. The writing is clear and succinct. If a term is introduced, it is defined. Although the chapters are not as detailed and encyclopedic as a textbook might be, this book captures enough information to help the physician prepare for the gastroenterology board examination or to provide useful review information. The pictures and graphs are colorful and clear; clearly written captions explain the visuals.

The added features are strong. Each section has suggested additional reading, and the index is comprehensive. One of the strongest features is the set of questions and answers at the end of each section. The questions are written in a multiple-choice format, which is the format of the board exams. Case histories are presented, and the reader is asked to consider what diagnosis is proper. The answers are then explained in detail. Also, abbreviations used in a specific section are explained at the beginning of the questions and answers.

As a random example is Section 1: the Esophagus and Gastroesophageal Reflux Disease (GERD), written by Joseph A. Murray, MD. After a brief introduction, the author clearly discusses etiology, factors contributing to GERD, the epidemiology of GERD, symptoms, establishing a diagnosis, diagnostic tests, and treatment. There are 11 charts and drawings and four full-color photos in 14 pages.

The strong, relevant, up-to-date, and interesting text made this book our top choice out of a total of 19 books. We recommend it not only for physicians and trainees in need of board review assistance but also for medical writers who may need powerful information for articles, grants, or other projects.

–Evelyn B. Kelly, PhD (chair); Robert Norman, DO; and Afsaneh Motamed-Khorasani

Medical Book Awards, Physician Category, Committee
**Invertebrate Medicine, 2nd edition**
Gregory A Lewbart, MSD, VMD, editor

The second edition of *Invertebrate Medicine* is a comprehensive text that reflects the current state of knowledge regarding the clinical assessment and medical treatment of diverse invertebrate species. Although *Invertebrate Medicine* includes some relevant anatomic and physiologic information, its focus is primarily on medicine and the treatment of disorders that affect both captive and wild invertebrates.

Comprising 29 chapters written by 33 different experts and organized by taxonomy, the book reviews a variety of invertebrates: sponges, gastropods, cephalopods, spiders, insects, honeybees, echinoderms, and many more. The textbook ends with several noteworthy chapters that address topics such as euthanasia, invertebrate animal welfare, and invertebrate health issues in conservation.

Because I write about disorders that affect the human species, my experience with invertebrates is limited primarily to spiders, butterflies, insects, and the occasional crustacean. Still, I found myself reading nearly every page to see the similarities between the treatment of human disease and invertebrate disease. Indeed, this book was an eye-opener. I was surprised to learn that just as we have reportable diseases in humans, there are about 20 reportable diseases of invertebrates mandated by the World Organisation for Animal Health (OIE), and there are other invertebrate diseases reportable to the United States Department of Agriculture (USDA).

The book has several elements that enhance the readability of material that, given its subject matter, could become dry and didactic discourse. Chapters are organized with headings and subheadings that give readers a clear idea of the content of each section. Bulleted lists break up the text and highlight important concepts. Diagrams and color and black-and-white photographs appear frequently to complement the content and make the book visually appealing. The MRI and echocardiographic images in particular would be invaluable to the animal health specialist. Also spot on are the well-organized tables in nearly every chapter. Each chapter concludes with a comprehensive list of references from which the reader can learn more.

Veterinarians, zoologists, biologists, aquatic medicine specialists, and others working in the fields of animal health and welfare will benefit from this thoughtful and well-referenced veterinary and husbandry textbook.

—Cyndy Kryder, MS, CCC-SP

The members of the Medical Book Awards, Health Care Professionals Category were Linda Felcone, MA; Terry Ann Glauser, MD, MPH; Debra L Gordon, MS; Cyndy Kryder (chair), and Phil Vinall, MBA
Handbook for Mortals consistently focuses on how relationships between the patient and family and loved ones, as well as health care providers, can be sustained and strengthened throughout the dying process. Practical, expert guidance is provided on specific treatment concerns (eg, pain control, hospice selection) and health insurance issues. In addition, chapters are devoted to the effects and progression of specific illnesses, the impact of sudden death, and the death of a child. Throughout, the authors directly and thoughtfully explain the range of situations likely to be encountered toward the end of life, as well as options to address them.

One of the book’s key themes is the importance of communication in improved quality of life at life’s end. For example, communicating treatment wishes to loved ones, or using legal documents to convey advance directives. Also covered are strategies to maximize patient-provider communication—as well as guidance on when to change these relationships if communication is not open. To help patients better navigate common medical and interpersonal situations, Handbook for Mortals presents common scenarios and potential talking points or “scripts” for readers. Also interspersed throughout are useful checklists, images, and brief poems and narrative reflections on death and dying. The poems and visuals provide excellent counterpoint to the main text, and the checklists are consistently useful.

Death is not a subject talked about casually or often in our society, but it should be discussed more often. As the authors note, “Talking about death does not make it happen, though many people are afraid it may.” The responsibilities and role-shifting that accompany end-of-life transitions can be overwhelming to both patients and their families—this book can help. Handbook for Mortals outlines the range of issues that can emerge for patients with advanced illness and provides guidance that is consistently empathetic and informed.

–Caitlin Rothermel, MA, MPHc

The members of the Medical Book Awards, Consumers Category, Committee were Nona Clifton; Dan Fernandez (chair); Alexandra Howson, PhD; Caitlin Rothermel, and Michele Vivirito.

For a list of books receiving Honorable Mention and Special Recognition, see the 2012 Book Awards page on the AMWA website.
President: Douglas Haneline, PhD, a teacher of literature and writing for more than 30 years, has been at Ferris State University in Michigan since 1984. He teaches research writing, advanced composition, medical writing, science fiction, American and British Literature, and Introductory Latin. Doug is a doctoral graduate of Ohio State University, with prior degrees from Middlebury College and the University of Delaware. Doug has been an AMWA member since 1986 and Fellow since 1992. His previous AMWA service includes national President-Elect; national Secretary; Administrator of Awards, Education, and the Annual Conference; chair and member of numerous committees and task forces; and President of the Michigan Chapter. Outside of AMWA, Doug served on the Michigan Humanities Council, the state affiliate of the National Endowment for the Humanities. He is an AQIP and PEAQ Peer Reviewer for the Higher Learning Commission.

Secretary: Stephen (Steve) Palmer, PhD, ELS, is an author’s editor in the Section of Scientific Publications at the Texas Heart Institute in Houston, TX. After earning his doctorate in social and health psychology at SUNY Stony Brook in 1999, Steve moved to Houston to conduct pain research as a postdoctoral fellow at the MD Anderson Cancer Center. He joined AMWA in 2002 and became a full-time medical writer at the Texas Heart Institute in 2003. Steve has served the Southwest Chapter in several capacities, including President and Chapter Delegate. On the EC, Steve has been Administrator of Chapters, Chapters & Membership, Annual Conference, and Awards and has served on the Membership and Constitution & Bylaws committees. He has been a judge for the Medical Book Awards and coordinator for poster presentations at the annual conference. He has also authored three articles published in the AMWA Journal. In his spare time, Steve
embraces new hobbies, which currently include cycling, tai chi, knife throwing, and cheese making.

**Treasurer: Christine F Wogan, MS, ELS,** is currently a Publications Program Manager at MD Anderson Cancer Center, where she provides a “one-stop editorial shop” for clinicians, scientists, and trainees in radiation oncology, physics, and biology. Her previous experience includes having a freelance grant-preparation business in the greater Boston area and being an experiment support scientist and later a senior scientific editor at NASA’s Johnson Space Center. She holds a BA in biology from Swarthmore College and an MS in human physiology from the University of Houston at Clear Lake. Chris joined AMWA in 1989 at the suggestion of friend and NASA colleague Jane Krauhs. She received AMWA’s President’s Award for exceptional and devoted service in 2010 and was named a Fellow in 2012. Her previous AMWA service includes the following: Budget & Finance Committee; Administrator of Awards; Southwest Chapter Director-at-Large, Treasurer, President, and Immediate Past President; and Annual Conference Editing/Writing Sections chair, workshop leader, open session panelist and moderator, and roundtable leader. She earned the Editor in the Life Sciences designation from BELS in 1991 and is also a member of the Council of Science Editors. In her spare time, Chris is an avid reader, hiker, downhill skier, and devotee of Asian cuisines. Though still a dyed-in-the-wool liberal Yankee at heart, after 25 years in Houston she reluctantly admits to a fondness for country music but still prefers traveling to cold climates.

**President-elect: Brian Bass** is an award-winning medical writer with more than 33 years of professional writing experience. He has specialized in medical communications for 27 years and has been a full-time freelance medical writer for 23 years. Brian’s company, Bass Global Inc, is a medical communications content development company providing medical writing and editing services to medical communications and education companies and medical advertising agencies. A member of AMWA since 1994 and an AMWA Fellow since 2001, Brian is a Past President of the Delaware Valley Chapter and has served as the Chair of the Princeton Conference for the past 16 years. Brian served most recently on the EC as Administrator of the Annual Conference for Sacramento, and he has also been the Administrator of Special Projects. He has been a workshop leader and open sessions presenter, and has chaired and been a member of numerous committees. Coauthor of *The Accidental Medical Writer*, Brian spends much of his free time giving presentations and writing books, a monthly newsletter, and other resources for people who want to launch and build their own successful freelance businesses. He loves to read, attend any type of live music concert, and occasionally sleep.

**Immediate Past President: Barbara Snyder, MA,** has 31 years of experience in medical writing for the pharmaceutical industry, starting as the first medical writer hired by Bristol-Myers. She has set up and led medical writing departments at Lorex Pharmaceuticals, Procter & Gamble Pharmaceuticals, and Warner Chilcott (US), LLC, and is currently Senior Director of Regulatory Services at Onconova Therapeutics, Inc. Barbara has been active in AMWA at both the chapter and national level for many years. She has held positions including President, President-Elect, Administrator of the Annual Conference, Administrator of Publications, Administrator of Development, Administrator of Education, member of the Budget & Finance Committee, Education Committee, Constitution & Bylaws Committee, Science Curriculum Task Force, Workshop Leader Benefit Task Force, Nominating Committee, Elections Task Force, Swanberg Award Committee, Eric Martin Award Committee (chair), the 2010 Executive Director Search Committee (chair), and President of the Ohio Valley Chapter. Her activities with the Annual Conference include chairing networking roundtables, serving as moderator and presenter for open sessions, and coordinating roundtable sessions. She received the President’s Award for outstanding service to AMWA in 2003 and was named a Fellow of the organization in 2006. In her spare time, Barbara rehabs houses to rent in a small town in Indiana, fishes for large-mouth bass, and wrangles two high-spirited Australian Shepherds.

**Administrator of the Annual Conference: Lori Alexander, MTPW, ELS,** joins the EC after 10 years as the AMWA Journal Editor, a position she was genuinely honored to hold. She is President of Editorial Rx, Inc., an independent medical writing and publishing company. Lori has more than 25 years of experience in medical communication, first as a medical editor at the Lahey Clinic and at the *Journal of Bone and Joint Surgery*, and then as a writer and editor in the Publications Department at the American Society of Clinical Oncology (ASCO). A member of AMWA since 1998, she is a Past President of the Florida Chapter and coordinated several chapter conferences for both the Mid-Atlantic and Florida chapters. She has been a member of numerous AMWA committees and has contributed to the annual conference as a roundtable leader, open session moderator, and workshop leader. She was recognized with the AMWA President’s Award in 2009, AMWA Fellowship in 2010, and a special award for her service to the *AMWA Journal* in 2012. She graduated from the University of New Hampshire with a degree in English (concentration in journalism) and earned a master’s degree in technical and
professional writing at Northeastern University in Boston. A Massachusetts native, she enjoys Florida living now, although she still roots for her “home teams.” Lori’s passions are humor, live theater, travel, seasonal decorating, penguins…and AMWA.

Administrator of Special Projects: Tamara Ball, MD, is a graduate of the University of Michigan (Go Blue!) and of the Johns Hopkins University School of Medicine. A perpetual student of fiction, she discovered medical writing after a 13-year career as an emergency department physician. She has enjoyed writing publications for Pharm Net-i3 for 6 years, where she is currently a Principal Medical Writer. Tami has been an AMWA member since 2004. Currently a member of the Carolinas Chapter, Tami previously served several roles on the Michigan Chapter, including President and Chapter Delegate. On the national level, she has served as the Administrator of Awards and Chapters & Membership and has chaired and served on several committees and task forces. For the annual conference, Tami has led workshops, roundtables, and Coffee Klatches, been a Conference Coach, chaired the Medical Book Awards (physician) committee, and been an open session speaker and moderator. Tami has also authored four articles published in the AMWA Journal. In her spare time, Tami is most commonly found trying to create the things she sees in her head, singing with a community chorus in languages she doesn’t know (Swahili, Georgian, Chechkin), and throwing objects for her border collie, Luca.

Certification Commission Chair: Karen Klein, MA, ELS, an AMWA member since 1989 and Fellow since 2006, is the Associate Director, Grant & Manuscript Development at Wake Forest University Health Sciences in Winston-Salem, NC. Karen was Secretary in 2011-2012 and has previously served on the EC as Administrator of Special Projects/Communications, Annual Conference Workshops, Publications, and Public Relations. She has led workshops, roundtables, open sessions, and Coffee Klatches at AMWA annual conferences. She has served as chair and member of numerous committees and task forces and has been published in the AMWA Journal. She earned the Editor in Life Sciences designation from BELS in 1991 and the designation of Certified Grant Professional in 2008 (successfully recertified in 2011). When not meeting grant deadlines—and to recover from them—she practices Bikram Yoga, follows the Carolina Hurricanes with her son Ben (although apparently not in 2012-13—curses on the NHL!), and chips away at the eternal reading list generated by her husband, Scott, an English professor at Wake Forest. She is honored and excited to be part of the medical writing certification effort and to continue on the EC.

Administrator of Education: Faith Reidenbach, ELS, CMPP, is a partner in Caley-Reidenbach Consulting, LLP. This will be her fourth year on the EC and she will lead a strategic committee and three subcommittees. One of the subcommittees is in charge of workshops, one will develop more resources to support workshop leaders, and one will plan how to put more educational opportunities online. In past years, Faith has been the Administrator of Awards, Publications, and Web & Internet Technology and a regular speaker at AMWA annual conferences, for which she created the popular event “Speed Networking.” For 4 years, she wrote a column for the AMWA Journal called “Tools and Trends in Medical Communication,” and she was a key contributor to the Annual Conference Blog during its early years. The accomplishments in which she takes greatest pride came during her 5 years on the Web & Internet Technology Committee. Along with Mary Royer, Faith was principally responsible for creating the Freelance Opportunities listserv and for convincing AMWA to create a group on a newfangled website called LinkedIn. In addition, she led the campaign that made the Freelance Directory freely accessible to prospective clients. Faith lives in rural Oregon, where she enjoys hiking, kayaking, birding by ear, human choral music, and way too many book groups.

Administrator of Chapters Relations: Katharyn (Kathy) Spiegel, PhD, is a Regulatory Writing Senior Manager at Amgen Inc. Before joining Amgen, Kathy spent 5 years running her own freelance writing and clinical trial consulting business. Prior to that, Kathy spent 18 years at Parke-Davis/Pfizer, first performing basic science research into the causes of Alzheimer disease, then medical writing, and finally as the clinical lead for a global epilepsy program. Kathy has a BS in chemistry from Duke University (Go Blue Devils!) and a PhD in pharmacology from Cornell University Medical College in Manhattan and completed a postdoctoral fellowship and instructor-ship at Albert Einstein College of Medicine in the Bronx. Kathy has been an AMWA member since 2006 and is on the EC for a second year, reprising her role as Administrator of the newly renamed department of Chapter Relations. Kathy is an avid, albeit amateur, equestrian and spends much of her free time riding her appendix quarterhorse gelding, Chip, playing her banjo, and making silver and copper jewelry.

Administrator of Online Community: Kristina (Tina) Wasson-Blader, PhD, ELS, CMPP, has more than 10 years of experience in writing and editing for science and medicine. In 2003, she moved to Oklahoma and started KWB Health Communications, Inc., a full-service writing and editing company that specializes in scientific and medical communications. Before that, she worked as a techni-
cal writer in a medical device company and as a marketing writer in a biotechnology company. Tina has a PhD in biology and completed an NIH-supported postdoctoral fellowship at Stanford University. She completed the AMWA Core Curriculum Certificate in 2007 and the Advanced Certificate in 2011. An AMWA member since 2002, Tina is a Past President of the Southwest Chapter. On the national level, Tina was on the Publications Committee, was a coordinator and editor for the AMWA Annual Conference open sessions reports for 5 years, was a Section Editor for the Professional Development section of the AMWA Journal for 4 years, and was the Administrator of Web and Information Technology for 1 year. When not chauffeuring her children to their activities, Tina enjoys reading, creating handmade cards, scrapbooking, and baking cakes.

Administrator of Publications: Anne-Marie Weber-Main, PhD, is Assistant Professor of Medicine and Research Medical Editor at the University of Minnesota-Twin Cities. Her primary work role is to increase the scholarly productivity of faculty members in the health sciences via individual/group mentoring, faculty development activities, and teaching, all focused on scientific writing and other research career competencies. She has closely mentored more than 90 fellows and faculty members engaged in producing over 300 written research products (grant proposals, articles). Anne Marie herself has co-written numerous proposals to fund research training programs and infrastructure for clinical research. She is also an author of several peer-reviewed journal articles and two scholarly books. In addition to her PhD in analytical chemistry, she completed a Mass Media Science and Engineering Fellowship from the American Association for the Advancement of Science, during which she produced science feature stories for CNN. Anne-Marie joined AMWA in 1998 and has served the North Central Chapter as President, a member of the Program Committee, and Chapter Delegate. She has been on several committees on the national level, has served in several capacities for the annual conference, and has been a manuscript reviewer for the AMWA Journal for 8 years. A Jersey Girl at heart, Anne Marie enjoys vacationing anywhere warmer than Minnesota (preferably near an ocean). Her greatest love is her family, which includes a gregarious 16-year-old daughter and an uber talented high school-teaching husband.

Administrator of Awards: Deborah Whippen has an extensive history of overseeing medical journals and leading publication efforts at nonprofit organizations. She currently is Vice President of Editorial Rx, Inc., a small medical writing and publishing company located in northern Florida, where she manages publications projects and journals, develops electronic applications, oversees educational materials, and is a continuing medical education consultant. Deb specializes in working with organizations whose missions involve the improvement of health care through educational and technological means. Deb has been a member of AMWA since 1989 and has served on the Public Relations and Publications Committees, as President of the Florida Chapter, and as Chapter Delegate. She enjoys making regular contributions to anysoldier.com, and she loves her family life, which includes rescue cats Grayson and Ellie; Florida; the ocean; words; the wind; and needlepoint.
## AMWA's Medical Writing Certification Initiative: Where Are We Now?*

**By Thomas P. Gegeny, MS, ELS, CMPP, and Karen Potvin Klein, MA, ELS, GPC**

*2011-2012 Chair and Chair-Elect, AMWA Certification Commission*

**APPENDIX.** Item Importance as Ranked by Survey Respondents

<table>
<thead>
<tr>
<th>Task or Knowledge, Skill, Ability</th>
<th>Score*</th>
<th>Mean</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presenting: Communicate scientific content appropriately</td>
<td>4.65</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Present the message logically and coherently</td>
<td>4.63</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Maintain confidentiality of information</td>
<td>4.62</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Apply proper mechanics: Apply proper word usage (general and medical), correct nomenclature, and nondiscriminatory language</td>
<td>4.56</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Apply proper mechanics: Construct effective sentences</td>
<td>4.56</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Develop clear, concise prose</td>
<td>4.55</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Retain the intended meaning of source materials or original documents</td>
<td>4.52</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Evaluating: Conduct critical review of a draft: Assess quality of writing</td>
<td>4.50</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Apply proper mechanics: Construct effective paragraphs</td>
<td>4.49</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Communicate statistical content appropriately</td>
<td>4.49</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Apply proper mechanics: Apply rules of grammar, spelling, and punctuation</td>
<td>4.48</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Evaluating: Identify inconsistencies in data or other content presented</td>
<td>4.47</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Presenting: Write document to adhere to standardized formats, guidelines, instructions, and ethical standards</td>
<td>4.40</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Interpreting: Comprehend relevant medical and scientific content: Understand terminology</td>
<td>4.40</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Evaluating: Evaluate collected information with regard to: Content</td>
<td>4.40</td>
<td>0.02</td>
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<tr>
<td>Presenting: Apply proper mechanics: Apply techniques for cohesion between paragraphs and sections</td>
<td>4.39</td>
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<tr>
<td>Gathering: Determine purpose of document</td>
<td>4.36</td>
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<tr>
<td>Interpreting: Respond to reviewers’ comments: Interpret feedback from reviewers</td>
<td>4.36</td>
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<tr>
<td>Interpreting: Respond to reviewers’ comments: Determine appropriate responses</td>
<td>4.34</td>
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<tr>
<td>Organizing: Structure content to communicate message</td>
<td>4.33</td>
<td>0.02</td>
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<tr>
<td>Interpreting: Synthesize and integrate information</td>
<td>4.32</td>
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<tr>
<td>Interpreting: Derive key message(s)</td>
<td>4.31</td>
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<tr>
<td>Presenting: Build logical and science-based arguments</td>
<td>4.31</td>
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<tr>
<td>Evaluating: Perform fact or data check</td>
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<tr>
<td>Gathering: Identify appropriate outlet. Identify relevant writing guidelines, instructions, and ethical standards</td>
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<tr>
<td>Evaluating: Conduct critical review of a draft: Provide options for solutions</td>
<td>4.27</td>
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<tr>
<td>Interpreting: Comprehend relevant medical and scientific content: Understand study design</td>
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<tr>
<td>Gathering: Identify context for document</td>
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<tr>
<td>Evaluating: Evaluate collected information with regard to: Appropriateness</td>
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<td>Evaluating: Conduct critical review of a draft: Evaluate the representation and description of data</td>
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<tr>
<td>Presenting: Tailor prose to the audience</td>
<td>4.23</td>
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<tr>
<td>Organizing: Identify and prioritize key elements of content</td>
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<td>Evaluating: Conduct critical review of a draft: Craft appropriate queries</td>
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<td>Presenting: Structure an abstract</td>
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<tr>
<td>Presenting: Apply principles of proofreading</td>
<td>4.18</td>
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</table>

*1=“of no importance,” 2=“of little importance,” 3=“moderately important,” 4=“very important,” and 5=“extremely important.”

SE: standard error.

*Appendix.* Item Importance as Ranked by Survey Respondents.
### APPENDIX (continued)

<table>
<thead>
<tr>
<th>Task or Knowledge, Skill, Ability</th>
<th>Score*</th>
<th>Mean</th>
<th>SE</th>
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<tbody>
<tr>
<td>Interpreting: Comprehend relevant medical and scientific content: Understand concepts</td>
<td>4.17</td>
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<td>Interpreting: Interpret clinical and numerical data</td>
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<tr>
<td>Organizing: Determine structure of tables and figures to best communicate data</td>
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<td>Presenting: Apply principles of visual presentation of data</td>
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<tr>
<td>Evaluating: Evaluate for completeness, fair balance, and absence of bias</td>
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<tr>
<td>Gathering: Identify target audience: Assess needs</td>
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<td>Evaluating: Evaluate collected information with regard to: Audience</td>
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<tr>
<td>Interpreting: Revise or repurpose existing content</td>
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<td>Evaluating: Conduct critical review of a draft: Recognize ethical considerations with respect to self and others</td>
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<tr>
<td>Interpreting: Comprehend review processes</td>
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<tr>
<td>Organizing: Design project work plan: Recognize roles, responsibilities, and processes</td>
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<tr>
<td>Interpreting: Determine inferences, implications, or clinical relevance</td>
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<tr>
<td>Organizing: Design project work plan: Develop timeline</td>
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<tr>
<td>Organizing: Determine organization of document</td>
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<tr>
<td>Organizing: Apply templates and guidelines to documents</td>
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<tr>
<td>Organizing: Design project work plan: Determine deliverables</td>
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<tr>
<td>Gathering: Identify appropriate outlet: Conduct a literature search</td>
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<td>Organizing: Determine process for tracking changes and version control</td>
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<tr>
<td>Organizing: Track progress and status of project</td>
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<tr>
<td>Interpreting: Comprehend relevant medical and scientific content: Understand statistical concepts</td>
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<tr>
<td>Gathering: Identify appropriate outlet: Identify relevant document models and templates</td>
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<td>Evaluating: Implement best approach to resolve issues</td>
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<td>Organizing: Determine which reference to cite in document</td>
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<td>Gathering: Identify appropriate outlet: Elicit information from collaborators and stakeholders</td>
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<td>Evaluating: Determine appropriate level(s) of editing</td>
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<tr>
<td>Presenting: Apply basic principles of design and layout</td>
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<tr>
<td>Gathering: Identify target audience: Identify knowledge gaps</td>
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<tr>
<td>Gathering: Identify appropriate outlet: Identify relevant sources</td>
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<td>Gathering: Select appropriate output type</td>
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<td>Organizing: Develop an outline</td>
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<tr>
<td>Gathering: Identify appropriate outlet: Identify necessary forms and supporting materials</td>
<td>3.74</td>
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<td>Organizing: Recognize and apply appropriate software and technology to use in developing the document</td>
<td>3.67</td>
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<tr>
<td>Organizing: Comprehend processes of developing and disseminating documents</td>
<td>3.60</td>
<td>0.04</td>
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</table>

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SE: standard error.
Dear Edie

No... "dear, dear, dear, dear, dear Edie."

I first met her when, in 1999, I asked her to be a guest speaker in my introductory biomedical writing course in the Biomedical Writing programs at the University of the Sciences. I couldn’t believe she said “yes.” She said “let’s go to dinner, instead.” So we did, my whole class, to a restaurant near where she lived in west Philadelphia. She sat like a queen before her subjects, at the head of the table, and answered questions for 2 hours. Shot from the hip. No research.

Then she took us on a tour of her fantastical home, two stories of bookcases, books packed up to the ceiling, and the full OED on a wooden pedestal in the middle of the room, like a shrine. She was sweet and warm and welcoming, but to me it felt like an audience with royalty.

I wrote her a couple of questions for her column over the following 10 years, but otherwise hadn’t any contact, besides taking her seminar at an AMWA meeting. Then came the request from the AMWA Journal for locals to visit Edie in the nursing home where she resided, post-stroke, to help her continue with her column. It was about an hour away from where I lived, and I jumped at the chance.

I walked into her room. She looked at me, blinked, and said “Kelly!” It had been easily 10 years since I had seen her. “I still have your CV in my files.”

I hugged her, we talked for over 2 hours, got caught up, and went to work on her column. Monthly visits turned to near-weekly visits. I’d walk in and she’d say “business or pleasure?” I’d look at her to see how fatigued she was, and if she was, I’d keep the AMWA questions in my bag, sit down, hold her hand, and complain to her about my mother, who was making me crazy. “She needs to grow up,” said Edie, once, and made me laugh.

I was mandated to bring her a chocolate milkshake every time I visited, made only with vanilla ice cream and chocolate syrup—not chocolate ice cream. Twelve ounces. I stopped at a Baskin-Robbins every time I went to see her, and had them make a chocolate shake—to her specs and defiantly had it put in a 14-ounce cup, for which I was fortunately not upbraided. Every time I walked into the Baskin-Robbins, they’d just start manufacturing the milkshake.

I’d sit, hold her hand, laugh, and listen to her regale me with stories about her once having set Isaac Asimov straight, how she never missed a deadline, and how she had to fire the occasional client. She’d wax eloquent about her pet peeves: use of the word “verbal” when the correct word was “spoken,” “vestigial tails,” such as using an unnecessary “-ical” at the end of a word (eg, “pharmacological” vs “pharmacologic”), and “effectiveness” vs “efficacy.”

The young nurses’ aides adored her; Edie referred to them as “just a doll, a doll,” and they smiled, call her “Miss Edie,” and reminded me continually that she was an important medical editor. Edie had a very mischievous streak in her. An aide was once talking about the important medical stuff Miss Edie did, and Edie said with complete, gentle authority, “You know, before the Ten Commandments were edited, the Seventh Commandment didn’t have the word ‘not’ in it.” The aide—who Edie knew was very religious—went wide-eyed. Edie strung her along for a bit, and then told her she was kidding. I was not up on my Commandments and I asked her what she had said, and Edie said, “well, the Seventh Commandment read ‘thou shalt commit adultery.’” And I was all like “jeez, Edie,” and she chuckled sweetly and said, “all in good fun.”

Working on Edie’s column with her was and remains the highlight of my medical writing career, and the most flattering opportunity I have ever had. Edie was sweet, funny, bright, and thankful for everything she had, right up to the end. I will miss her, badly.

—Kelleen Flaherty
Jamison, PA

Never a national office-holder, never an office-seeker, Edie Schwager nevertheless won the minds and hearts and love of a majority of us in AMWA. While many AMWA members and officers will mourn her passing with brilliant testimonials, many more will mourn her with quiet, silent heartfelt grief.

I first met Edie in the early 1960s at a Delaware Valley Chapter meeting in Philadelphia, both of us having recently joined AMWA. My late wife, Anita, and I soon became fast friends with her, both professionally and personal...
sonally—a friendship that lasted over 50 years. My greatest personal tribute to her is that this then-secretary with no college training soon had all of us with college and graduate degrees, many with important editorial positions, sitting at her feet to learn about the English language. What a tremendous achievement!

Without fanfare or bragging, Edie accomplished so many things in AMWA. Let me count the ways.

Before she started with AMWA, she had been a potent and highly regarded book editor for Hahnemann Medical College.

For all the 50 years I knew her, she managed to maintain friendships in AMWA, good friendships, with many contemporaries of each period (who changed any number of times through the years), and she continued to do that until her death. Each generation of AMWA had multiple connections with her.

In those 50 years, I never heard her speak disparagingly of others, nor did I ever hear anyone demean Edie.

She was held in highest regard for her command of grammar and usage by practitioners of the English language, experienced and beginners, young and old, executives and those just starting out. She taught them, and they listened—and all of them learned. She never held back, always trying to teach and help other writers.

Edie established a reputation for her clever and ingenious titles, especially for her lectures—such classics as “The King’s English—and so is the Queen” and “Dangerous Dyads and Troublesome Triads.” And there was no let-down when she got deep into the topics; she was teaching all the way.

And what can one say about Dear Edie? Her brilliant column in our Journal attracted hundreds of readers each issue and offered a multitude of pearls. I would say that my dear and true friends, to whom I owe so much, with love and gratitude, that was just the first of many. We were both enthralled with her workshop—well-chosen materials, clear and vivid teaching all the way.

Edie was the heart and soul of AMWA. I first met her in Philadelphia in the spring of 1989 when I attended her workshop at a regional conference for Women In Communications (WIC; now The Association for Women in Communications). At the time, I had never heard of AMWA, but I subsequently became a member and attended my first annual conference that fall. Much to my surprise, I found myself in an elevator with Edie and mentioned participating in her workshop at the WIC conference. We had a delightful conversation that day and, gratefully, that was just the first of many. We were both members of the Delaware Valley Chapter (DVC), so I had the good fortune to interact with Edie at monthly chapter meetings and at annual conferences. After I moved to Florida in 2000, Edie never stopped teasing me about “deserting” the DVC. In my mind’s eye, I will always see her “holding court” in the hospitality area at the AMWA annual conference. She truly was “dear” to all who knew her.

—Mary E. Knatterud
St. Paul, MN

At my very first national AMWA conference back in 1990, in Los Angeles, I took dear Edie Schwager’s no-nonsense, yet empathetic and fun, workshop on medical (ab)usage—and, as soon as I could afterward, devoured her book on the same topic. At that time, I was relatively new to the profession of medical writing, but she treated me, from that first homework assignment of hers on, as an intellectually interesting friend; I returned to my University of Minnesota surgery department brimming with excitement over having met her and so many other intriguing colleagues. At every fall conference for nearly 2 decades, she greeted me (and my twin sons, who came with me on many AMWA adventures to various vibrant cities, from Baltimore to San Diego) with genuine warmth. She always answered my fairly frequent queries in her column with consummate skill and respect. For these past few years, I have truly missed running into her and reading her.

I know she relished pithy literary and rhetorical quotes, often sprinkling them in the margins of the AMWA Journal. I once shared with her one of my favorites, by Zelda Sayre Fitzgerald, that seems so apt for medically oriented wordsmiths who, in my view, must always resist the urge to become too quantitative or bureaucratic: “Nobody has ever measured, not even poets, how much the heart can hold.” Edie was an exemplar of what a full measure of personable, even poetic AMWA collegiality, at its best, can mean: savvy point by savvy point, sincere heart to sincere heart.

Thanks and blessings to Edie forever, and to her family.

—Donna Miceli
Ft. Myers, FL
Edie’s conversation—always polite, always witty, always upbeat, and spiced with a nonstop sense of the absurd and brimming with a wealth of allusion from classical languages to literature, from music to art, and from science to medicine. Edie as a mentor—whether with a new member or an acquaintance of many years, always asking about one’s career and offering encouragement. Edie aging gracefully—active into her 90s and realistically accepting the limitations age and health issues placed on her, setting an example for all of us younger than her but headed in the same direction. Edie constantly reminding us with every word and gesture of the importance of living life to the fullest.

What an editor! What a teacher! What a woman!

—Doug Haneline
Big Rapids, MI

We first met when I took her workshop about 12 years ago. The workshop content included much that was familiar to me, but Edie’s gentle humor made the experience more fun than I expected. We subsequently chatted and laughed at every annual conference, even those last few, when she relied on a walker to move around. She had far more resilience than one would expect, given how petite and bird-like she was. Although we never worked together outside of the context of the AMWA conference, each encounter I had with her made me admire and like her more. Since medical writing is a third or fourth career for me, and I intend to live—and possibly keep teaching AMWA workshops—until I’m in my 90s, I thought of Edie as a role model, someone who kept giving back to the AMWA community long after many people of her age had settled permanently into a rocking chair. I missed her at the past two conferences—I miss her even more, now.

—Jane Neff Rollins
Montrose, CA

My daughter spoke for herself and for me and so many: “She makes me feel that I am a special friend, and that I deserve to be.”

—Guy Whitehead and Amelia Whitehead
Rochester, MN

Edie will be greatly missed by those of us who looked forward to her column in the AMWA Journal. “Dear Edie” was always the first section of the Journal I read when each issue was delivered. I was also privileged to attend one of her workshops nearly 20 years ago, and I still remember that workshop far and above the many other AMWA sessions I’ve attended through the years. Edie’s love and knowledge of the language was evident, and she made an indelible impression on me of the importance of writing clearly and succinctly and using just the right word in the right place. She championed the mastery of writing clearly and thoughtfully that has been lost to many medical communicators today. Her precise and thorough handling of questions about difficult writing issues from the AMWA membership was always handled with expertise and humor. Her excellent books on medical writing will continue to have a prominent place in my reference library.

—Larry East
Research Triangle Park, NC

My daughter spoke for herself and for me and so many: “She makes me feel that I am a special friend, and that I deserve to be.”

—Guy Whitehead and Amelia Whitehead
Rochester, MN